



State of Tennessee

Health Services and Development Agency

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Date: October 9, 2015

To: HSDA Members

From: Melanie M. Hill, Executive Director

**Re: CONSENT CALENDAR JUSTIFICATION
CN1508-032 Tennova Healthcare--LaFollette Medical Center**

As permitted by Statute and further explained by Agency Rule later in this memo, I have placed this application on the Consent Calendar based upon my determination that the application appears to meet the established criteria for granting a certificate of need. Need, Economic Feasibility and Contribution to the Orderly Development of Health Care appear to have been demonstrated as detailed below. If Agency Members determine that the criteria have been met, a member may move to approve the application by adopting the criteria set forth in this justification or develop another motion for approval that addresses each of the three criteria required for approval of a certificate of need. If you find one or more of the criteria have not been met, then a motion to deny is in order.

At the time the application entered the review cycle on September 1, 2015, it was not opposed. If the application is opposed prior to it being heard, it will be moved to the bottom of the regular October agenda and the applicant will make a full presentation.

Summary

Tennova Healthcare--LaFollette Medical Center (TH--LMC) proposes to initiate mobile extracorporeal lithotripsy services up to 3 days per week. The 66-bed hospital is owned by Campbell County HMA, LLC and affiliated through several subsidiaries with Community Health Systems, Inc. based in Franklin, Tennessee. The estimated project cost is \$440,203.

The Agency has previously directed that lithotripsy applications be placed on CONSENT when possible due to the significant decline in equipment cost.

Extracorporeal lithotripsy is a procedure that pulverizes urinary stones by means of a special machine called a lithotripter. The lithotripter generates shockwaves from outside the body. The waves travel through the body until they reach the stone shattering it. This permits the stone fragments to pass through the urinary tract. When lithotripsy was first utilized in the early 1980's, the lithotripsy system consisted of a large tub, an imaging system, and a large lithotripter to generate the shockwaves. The patient was placed in the tub filled with water, the stones were located by the imaging system, and the lithotripter generated the shockwaves to pulverize the stones. The equipment was large and costly. Equipment has evolved significantly since that time. The lithotripsy system is smaller, more powerful, and less costly. Supplemental 1 includes a picture and description of the lithotripsy system to be acquired.

TH--LMC will operate the lithotripsy service as part of the hospital's surgical department. It will contract with the mobile vendor Kentucky 1 who will provide the HealthTronics- LithoDiamond Multifunctional Lithotripsy System and a radiological technologist. Under the terms of the contract, the hospital provides the space for the unit (typically the cystology procedure room in the surgery department), the urologist, the CRNA, the supplies, and the medication. The mobile vendor delivers the lithotripsy unit to the hospital where it will be rolled off the transport truck and into an operating room.

The need formula underestimates the need for services in the area. The need rate is 128 yet 148 service area residents actually received lithotripsy services outside the service area in 2013. TH--LMC projects 165 treatments in Year 1 and 180 treatments in Year 2. In August 2015, a Board-certified urologist, Sean Delair, M.D., relocated his urology practice from Kentucky to LaFollette. Due to his training and extensive experience in providing lithotripsy services and the number of patients seeking services outside the service area, the hospital sought approval for this service.

The approval of this application should improve access to care and reduce outmigration since TH-LMC is contracted with Amerigroup, BlueCare, United Health Community Plan and TennCare Select. The hospital projects the Medicare/Medicaid payor mix to be 59.5%/17.6%.

The project requires no construction and will be funded by cash reserves of the parent company. The contract with the vendor includes a per click (per procedure) lease so there is little financial risk.

Please refer to the staff summary and the TDH report for a detailed narrative of the project.

Executive Director Justification -

I recommend approval of certificate of need application CN1508-032 to initiate mobile lithotripsy services up to 3 days per week based upon my belief the following general criteria for a certificate of need have been met.

Need- Need is met, as this service will improve access to lithotripsy services especially for older citizens and the TennCare population. The availability of a urologist in the service area who will utilize the service should reduce outmigration and the costs associated with it (travel time for patients and the costs associated with travel-including time off work and fuel costs).

Economic Feasibility- Economic Feasibility is met as Community Health Systems, the parent company, has committed to funding the project. Since there is no actual capital outlay due to the per-click lease arrangement, there is little financial risk.

Contribution to the Orderly Development of Health Care- Orderly Development is demonstrated since this will make the service available to residents who currently are required to travel out of the service area for treatment.

Statutory Citation -TCA 68-11-1608. Review of applications -- Report

(d) The executive director may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

Rules of the Health Services and Development Agency-- 0720-10-.05 CONSENT CALENDAR

(1)Each monthly meeting's agenda will be available for both a consent calendar and a regular calendar.

(2)In order to be placed on the consent calendar, the application must not be opposed by anyone having legal standing to oppose the application, and the executive director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.

(3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with The Agency within thirty (30) days of the beginning of the applicable review cycle.

(4)If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by The Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of The Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.

(a) For purposes of this rule, the "next regular agenda" means the next regular calendar to be considered at the same monthly meeting.

(5)Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
OCTOBER 28, 2015
APPLICATION SUMMARY

NAME OF PROJECT: Tennova Healthcare – LaFollette Medical Center

PROJECT NUMBER: CN1508-032

ADDRESS: 923 Central Avenue
LaFollette (Campbell County), TN 37762

LEGAL OWNER: Campbell County HMA, LLC
923 Central Avenue
LaFollette (Campbell County), TN 37762

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Jerry Taylor
(615) 724-3247

DATE FILED: August 14, 2015

PROJECT COST: \$440,203.00

FINANCING: Cash Reserves

PURPOSE FOR FILING: Initiation of mobile Extra-Corporeal Shockwave
Lithotripsy up to 3 days per week

DESCRIPTION:

Tennova Healthcare d/b/a LaFollette Medical Center (TH-LMC), a 66 licensed bed acute care hospital owned by Community Health Systems, is seeking to initiate a mobile Extra-Corporeal Shockwave Lithotripsy (ESWL or Lithotripsy) service up to 3 days per week using existing operating room resources on its main hospital campus. The project involves the lease of an existing mobile ESWL unit. The project does not involve any renovation or new construction. This application has been placed under **CONSENT CALENDAR REVIEW** in accordance with TCA §68-11-1608(d) and Agency Rule 0720-10-.05

SPECIFIC CRITERIA AND STANDARDS REVIEW:
EXTRA-CORPOREAL SHOOCKWAVE LITHOTRIPSY

1. **Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + 0$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

0 = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

Using estimates of need for ESWL services published by Health Statistics, TDH, the applicant identified the use rate, population and estimated need for the primary service area (PSA), including Campbell, Claiborne, and Scott Counties. The need in the PSA is estimated at 128 lithotripsy procedures in calendar year (CY) 2018.

The applicant meets this criterion.

2. **Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at

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least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

The applicant estimates 165 total procedures in Year 1 for its proposed 3 day per week mobile service. The pro-rated minimum volume is 150 procedures (3/5 of 250) per year.

The projected utilization of the mobile service meets this criterion.

- 3. Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

There are no ESWL providers located within the applicant's 3 county service area.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

Using 2013 HDDS data from the Tennessee Department of Health, the applicant identified Methodist Medical Center of Oak Ridge (Anderson County), North Knoxville Medical Center (Knox County), and the University of Tennessee Medical Center (Knox County) as providing 148 ESWL procedures to residents

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in the 3 county service area. The table is located in Attachment C.I, Need 1.

Using 2014 HSDA Equipment Registry data pertaining to patient destinations for ESWL services, residents of the applicant's proposed 3-county PSA represented approximately 132 lithotripsy procedures in CY2014. Of this amount, 101 procedures or 76.5% were performed at provider sites in Knox County, with the remaining 31 procedures or 23.5% performed in Anderson County.

The applicant meets this criterion.

4. **Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

There are no existing lithotripsy providers in the 3 county service area.

5. **Adequate Staffing and Services:** The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:
- a. The existence of an active radiology service and an established referral urological practice;
 - b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and
 - c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

- A) *The applicant documented the qualifications of its physician medical staff participating in the service;*
- B) *Acute inpatient services in both Anderson and Knox Counties for possible patient complications are located under 50 minutes' drive time from the applicant;*
- C) *The equipment vendor under agreement will properly train and certify the technologist who will operate the Lithotripsy Service.*

The applicant will meet this criterion.

6. **ESWL Equipment:** Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

Documentation of FDA approval is provided in the application.

The applicant meets this criterion.

7. **Quality Control and Monitoring:** The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

The applicant's plans to develop, implement, and maintain clinical policies and procedures for the proposed hospital service line were addressed in the application. The policies and procedures will be developed to incorporate TDH licensing and Joint Commission Accreditation standards.

It appears that the applicant will meet this criterion.

8. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant states that it will provide statistics regarding the proposed ESWL service.

The applicant will meet this criterion.

9. **Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

The hospital has an existing transfer agreement with UT Medical Center in Knoxville, the closest Level 1 Trauma Center hospital located approximately 48 miles from LaFollete (Campbell County), TN.

The applicant meets this criterion.

10. **Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

- a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All of the 3-county service area is designated as a medically underserved area.

- b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

The use rate by service area residents (Lithotripsy procedures per 1,000 population) compared to the statewide resident use rate from 2012 - 2014 is illustrated in the following table.

ESWL Use Rates per 1,000 Population in TH-LMC's Service Area

County	2012	2013	2014
Campbell	1.93	2.13	1.51
Claiborne	1.26	1.04	.98
Scott	1.95	1.54	1.68
Statewide	1.13	1.17	1.21

Source: HSDA Equipment Registry

Using HSDA Equipment Registry Data, two of the three Counties in the service area exceeded the state use rate in 2014. Claiborne County fell below the state use rate in 2013 and 2014, but exceeded the state use rate in 2012. However, Department of Health data indicates all three counties had a higher lithotripsy use rate than the state-wide use rate for 2013.

- c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

TH-LMC receives Essential Access Program Payments.

It appears that the applicant meets the criteria for this section.

Staff Summary

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

Tennova Healthcare-Lafollette Medical Center, a 66 licensed bed hospital at 923 Central Avenue in Lafollette, Tennessee, is seeking approval to initiate a mobile Extra-Corporeal Shockwave Lithotripsy (ESWL or lithotripsy) service on its campus up to 3 days per week. If approved, the service will operate out of existing operating room suites of the hospital. No renovation or new construction costs will be necessary. If approved, the applicant plans to initiate the proposed mobile ESWL in December 2015. This application has been placed under **CONSENT CALENDAR REVIEW** in accordance with TCA §68-11-1608(d) and Agency Rule 0720-10-.05

The applicant initially plans to operate the mobile lithotripsy service one day per week until volume justifies additional days. The days the mobile lithotripsy unit will be scheduled at TH-LMC have not been determined by the applicant.

In the supplemental response, the applicant describes the use of lithotripsy as an alternative to invasive surgeries that is very low risk, non-invasive, and less painful with an 80%-90% success rate.

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In August 2015, Dr. Sean Delair, a board certified Urologist joined the medical staff of TH-LMC. Prior to August 2015, TH-LMC did not have an urologist on its medical staff. In the supplemental response, the applicant notes TH-LMC is continuing to explore opportunities that may result in another Urologist joining the hospital's medical staff.

TH-LMC's total licensed bed complement consists of 66 licensed hospital beds as follows: 50 medical/surgical, 6 ICU/CCU, and 10 geriatric psychiatric beds. According to the 2013 Joint Annual Report all the 66 licensed beds are staffed. Based on 27,985 total inpatient days, the hospital's licensed and staffed hospital bed occupancy in 2013 was 57.3%. According to the Department of Health and pertaining to the Joint Annual Reports, the following defines the two bed categories:

Licensed Beds- The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).

Staffed Beds-The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

Ownership

- Tennova Healthcare-Lafollette Medical Center is owned by Knoxville HMA Holdings, LLC, which is a wholly owned indirect subsidiary of CHS/Community Health Systems, Inc.
- Ownership information is provided in Attachment B.I., Project Description.

Facility Information

- No renovation or construction is involved with this project.
- The service will be located in the hospital surgery department's existing cystology procedure room, or in one of the two existing operating rooms.
- The applicant states no renovation or new construction will be necessary to accommodate the mobile lithotripsy unit.
- A floor plan drawing of the proposed site is included as Attachment B.IV.

Mobile ESWL Equipment

- The proposed mobile lithotripsy unit owned by Kentucky 1 Lithotripsy was manufactured in July 2005, been in service since its manufacture date, and has an expected useful life of 20 plus years.

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- A 6 page description of the mobile Health Tronics Lithodiamond Multifunctional Lithotripsy System is included in supplemental #1.
- The vendor quote documents an initial 1-year lease cost of \$396,000.00 which is based on a \$2,400 per procedure or “per click” rate. This amount is higher than the ESWL unit’s estimated fair market value of \$120,000.00.

Project Need

The following items summarize the need for the project:

- There is no lithotripsy unit located in the 3 County service area.
- The closest lithotripsy units are located in Knox and Anderson County which is a 1 ½ hour to 2 hour patient round trip.
- For the years 2013-2015 an average of 358 patients per year were discharged from the TH-LMC emergency department with a diagnosis of “Possible Urology” with a percentage of those patients possibly being lithotripsy candidates.
- In August 2015 a board certified Urologist trained and experienced in delivering lithotripsy treatments joined the medical staff of TH-LMC.

The applicant identified the need for the project using 2013 ESWL estimates developed by TDH for the 3-county service area. The following is the latest 2014 HSDA Equipment Registry data pertaining to ESWL patient volumes by county of residence. The information is illustrated in the table below.

Service Area ESWL Projected Need Compared to Resident Use					
County	2018 Population	Estimated Need (ESWL Procedures)	Resident Procedures (2014)	Resident Procedures at Anderson County Sites (2014)	Resident Procedures at Knox County Sites (2014)
Campbell	41,654	54	63	15	48
Claiborne	34,263	44	32	0	32
Scott	23,058	30	37	16	21
Total	98,975	128	132	31	101

Sources: Estimate of Need by County, 8/14 TDH document; ESWL patient origin data, HSDA Equipment Registry

- Using 2014 HSDA Equipment Registry data pertaining to patient destinations for ESWL services, residents of the applicant’s proposed 3-county PSA received approximately 132 lithotripsy procedures in CY2014.
- Of the 132 procedures, 101 procedures or 76.5% were performed at provider sites in Knox County, with the remaining 31 procedures or 23.5% performed in Anderson County.

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Applicant's ESWL Service Area

The primary service area of the applicant's proposed new lithotripsy service is Campbell, Claiborne, and Scott Counties. Collectively, these counties accounted for 89% of the hospital's inpatient admissions at TH-LMC in 2013.

- The total population of the combined 3-county service area is estimated at 96,463 residents in calendar year 2015 increasing by approximately 1.4% to 97,815 residents in CY 2018.
- The total population of the state of Tennessee is expected to grow 2.8% from CY2015 to CY2018.
- The total 65+ age population is estimated at 17,408 residents in CY 2015 increasing approximately 5.5% to 18,357 residents in 2018 compared to a statewide change of 8.8% during this time period.
- The age 65 and older population accounts for approximately 18.0% of the total service area population compared to 15.2% statewide.
- The applicant estimates that approximately 31.5% of the residents in the 3 County service area are enrolled in TennCare compared to 21.6% statewide.

Historical Utilization

Residents of the service area are traveling to ESWL providers primarily in Anderson and Knox County. The outmigration to other providers is shown in the table below.

ESWL Provider Historical Utilization by PSA Residents

	2012	2013	2014	% Change '12-'14
Knox County				
Total # resident ESWL procedures	163	156	132	-19%
# residents using Knox Co. Providers	112	115	101	-9.8%
% Residents using Knox Co. providers	68.7%	73.7%	76.5%	7.8%
Total ESWL procedures of Knox Co. providers	1,456	1,573	1,439	-1.1%
% Knox Co. provider reliance on PSA/SSA residents	11.2%	9.9%	9.2%	-2%
Anderson County				
# residents using Anderson Co. Providers	51	40	31	-36.22%
% Residents using Anderson Co. providers	31.3%	25.6%	23.5%	-7.8%
Total ESWL procedures of Anderson Co. providers	212	192	168	-20.7%
% Anderson Co. provider reliance on PSA/SSA residents	24.1%	20.1%	18.4%	-5.7%

Source: CN1508-032, Supplemental #1

Based on the table above, the following highlights are noted:

- The number of ESWL procedures for residents of the 3 county service area in Knox and Anderson Counties decreased 23.4% from 163 in 2012 to 132 in 2014.
- On average, approximately 73% of the 3 County service area resident's total ESWL procedures were performed at Knox County provider sites from 2011 - 2013.
- Knox County ESWL provider dependence on residents of the applicant's service area averaged approximately 10.1% of Knox County provider volumes from 2011 to 2013.

Projected Utilization

- The applicant projects 165 procedures in Year 1 increasing to 180 procedures in Year 2.
- The applicant notes the service area has already exceeded the statewide projected statewide use rate of 128 procedures in 2018 by the fact 148 procedures were performed in 2013.
- The applicant expects additional patients will seek lithotripsy services in the service area that were previously unable or unwilling to leave the service area to receive the services.

Project Cost

Major costs are:

- Renewable one year lease of a HealthTronics LithoDiamond Lithotripter at a "per click" rate of \$2,400 per procedure. Total payments are estimated at approximately \$396,000 (165 procedures x \$2,400/procedure).
- There are no costs for renovation or new construction associated with this project.
- For other details on Project Cost, see the revised Project Cost Chart on page 24 of the original application.

Historical Data Chart

The ESWL service is a new service line for the hospital with no record of fiscal operations. Highlights of the applicant's overall financial performance are as follows:

- According to the Historical Data Chart TH-LMC experienced profitable net operating income results for one of the three most recent years reported: \$5,608,000 for 2012; \$7,422,408 for 2013; and \$7,513,932 for 2014.
- Average Annual Net Operating Income less capital expenditures (NOI) was favorable at approximately 14% of annual net operating revenue for the year 2014.

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Projected Data Chart

Proposed Lithotripsy Service

Total gross operating revenue of the applicant's new mobile lithotripsy service is \$1,540,704.00 on 165 procedures in Year 1 increasing by approximately 9.1% to \$1,680,768.00 on 180 procedures in Year Two. The Projected Data Chart reflects the following:

- Net operating income amounts to \$94,278.00 in Year 1 and \$102,848.00 in Year 2.
- The operating margin of the new ESWL service amounts to approximately 6.1% of gross revenue in Year 2.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to reach \$560,160.00 or approximately 33.3% of total gross revenue in Year Two.

LaFollette Medical Center

- The applicant projects \$244,191,655.00 in total gross revenue during the first year of operation (2015) and \$250,816,346 in Year Two (2016).
- Net operating income less capital expenditures will equal \$8,152,633 in Year 2017 increasing to \$9,077,707 in Year 2018.

Charges

A summary of the applicant's charges for Year 1 of the project is as follows:

- The proposed average gross charge is \$9,338/ procedure in 2015.
- The average deduction is \$6,225/procedure, producing an average net charge of \$3,112/procedure.
- According to the HSDA Equipment Registry, the applicant's \$9,338.00 gross charge falls below the 2014 ESWL 1st Quartile charge of \$9,459.18.

Payor Mix

- The expected payor mix in Year 1 includes 59.5% of gross operating revenue for Medicare and 17.6% for TennCare.
- The hospital contracts with all TennCare MCOs in the service area: AmeriGroup, Blue Care, United Healthcare Community Plan, and TennCare Select.

Financing

- While there is no significant capital outlay or start-up costs for the project, the parent company will provide funding support from cash reserves if necessary.
- A July 15, 2015 letter from Anita H. Passarella, Director of Treasury Management of Community Health Systems, confirms that the parent company has sufficient cash reserves to fund the proposed project.

The applicant submitted audited financial statements of Community Health Systems, Inc. for the period ending December 31, 2014. Review of the Consolidated Balance Sheets of these entities revealed the following:

Parent	Cash & Cash Equivalentents	Current Assets	Current Liabilities	Current Ratio
Community Health Systems, Inc.	\$509,000,000	\$5,566,000,000	\$3,589,000,000	1.55 to 1

Source: Excerpted from Attachment C., II, Economic Feasibility-10 of the application.

Note to Agency members: *Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.*

Staffing

The applicant's proposed direct patient care staffing in Year One includes the following:

Position Type	FTEs
Registered Nurses	0.32
Surgical Tech	0.32
CRNA	0.32
Total	0.96

Source: CN1508-032

Licensure/Accreditation

- LaFollette Medical Center is accredited by The Joint Commission and licensed by TDH.
- A copy of the most recent Joint Commission survey is located in Attachment C, III, Orderly Development, 8.

The applicant has submitted the required information on corporate documentation, site control and a quote for the 1-year renewable lease of the mobile ESWL unit. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in three years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied applications, or outstanding certificates of Need for this applicant.

Note: Community Health Systems, Inc. has a financial interest in this project and the following:

Pending Applications

Gateway Medical Center Satellite Emergency Department at Sango, CN1507-027, has a pending application that will be reviewed simultaneously with NorthCrest Medical Center, CN1507-028, at the October 28, 2015 Agency meeting. The applicant is seeking Certificate of Need approval for the construction and establishment of a satellite emergency department at an unaddressed site on the north side of Highway 76, approximately 1,400 feet east of I-24 at Exit 11 in Montgomery County, Tennessee, 37040. The proposed facility will be operated under the license of Gateway Medical Center and will have 8 treatment rooms providing Levels I through V emergency treatment services. The facility will also provide ancillary services, including, medical lab, CT, X-Ray and Ultra-Sound, at a minimum. The project involves no new licensed inpatient hospital beds, no new healthcare services being initiated and no major medical equipment. The estimated project cost is \$11,000,000.00.

Outstanding Certificates of Need

Tennova LaFollette Health and Rehab Center, CN1505-021, has an outstanding Certificate of Need that will expire on October 1, 2017. The proposed project was approved at the August 26, 2015 Agency meeting to renovate approximately

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26,350 of the existing 35,317 square foot facility at a construction cost in excess of \$2 million. The project focuses on cosmetic finishes, changes in nurse's stations, patient day rooms and patient dining areas of the building and does not involve changes to any existing services or the licensed bed complement. **The estimated project cost is \$3,202,189.** *Project Status: The project was recently approved.*

Metro Knoxville HMA, LLC d/b/a Tennova Healthcare, CN1408-033A, has an outstanding Certificate of Need that will expire on January 1, 2019. The project was approved at the November 19, 2014 Agency meeting for the partial replacement and relocation of 272 of 401 beds from Physicians Regional Medical Center from 900 E. Oak Hill Avenue, Knoxville (Knox County) to a site at the intersection of Middlebrook Pike and Old Weisgarber Road across from Dowell Springs Boulevard, Knoxville (Knox County), a distance of approximately nine (9) miles from the current facility. The estimated project cost is **\$303,545,204.00**. *Project Status: Per a progress report provided on 07/31/2015 by a representative for Tennova Healthcare, preliminary due diligence was completed in March of 2015. Since that time, more in depth site evaluation has been initiated, including site utility and wetlands assessment. In June 2015, the land purchase option for the campus was extended for an additional 6 months to allow for completion of the due diligence. It is anticipated that the option will be exercised and the land purchased in early 2016. Site construction is projected to start in May 2016 with a project completion date of July 2018.*

Metro Knoxville HMA, LLC d/b/a Tennova Healthcare, CN1406-034A, has an outstanding Certificate of Need that will expire on January 1, 2019. The project was approved at the November 19, 2014 Agency meeting for the replacement and relocation of the 25 bed nursing home which is located in Physicians Regional Medical Center. The nursing home proposed to relocate from the hospital from 900 E. Oak Hill Avenue, Knoxville (Knox County) to a site at the intersection of Middlebrook Pike and Old Weisgarber Road across from Dowell Springs Boulevard, Knoxville (Knox County), a distance of approximately nine (9) miles from the current facility. The estimated project cost is **\$6,454,796.00**. *Project Status: Per a progress report provided on 07/31/2015 by a representative for Tennova Healthcare, preliminary due diligence was completed in March of 2015. Since that time, more in depth site evaluation has been initiated, including site utility and wetlands assessment. In June 2015, the land purchase option for the campus was extended for an additional 6 months to allow for completion of the due diligence. It is anticipated that the option will be exercised and the land purchased in early 2016. Site construction is projected to start in May 2016 with a project completion date of July 2018.*

Dyersburg Regional Medical Center, CN1403-007A, has an outstanding Certificate of Need that will expire on September 1, 2017. The project was

**TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER
CN1508-032**

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approved at the July 23, 2014 Agency meeting for the expansion of Diagnostic Cardiac Catheterization Services, currently limited to diagnostic procedures, to include interventional (therapeutic) cardiac catheterization procedures at Dyersburg Regional Medical Center, Dyersburg (Dyer County), Tennessee. The estimated project cost is **\$367,763**. *Project Status: Per a status update provided on July 20, 2015, some equipment has been purchased and is on-site, while other equipment has been ordered and will arrive soon. An off-site training schedule has been developed with Methodist Health Care in Memphis.*

Metro Knoxville, HMA, LLC d/b/a Tennova Healthcare-North Knoxville Medical Center, CN1211-056A, has an outstanding Certificate of Need that will expire on April 1, 2016. The CON was approved at the February 27, 2013 Agency meeting for the initiation of diagnostic cardiac catheterization services. The project involves construction and equipping of shell space within the hospital to serve as a dual cardiac catheterization/vascular lab, support areas for the lab, expanded waiting room, and additional pre-operative and post-operative space. The estimated project cost is **\$4,377,421.00**. *Project Status: Per an annual progress report provided on 04/09/2015 by a representative for CHS, the anticipated date of project completion was May 15, 2015. A final project report is pending.*

HMA Fentress County Hospital, LLC d/b/a Jamestown Regional Medical Center, CN1211-055A, has an outstanding Certificate of Need that will expire on April 1, 2016. The CON was approved at the February 27, 2013 Agency meeting for the conversion of 6 existing acute care hospital beds to swing beds located at 436 Central Avenue West, Jamestown (Fentress County). The estimated project cost is **\$30,677.00**. *Project Status: Per an annual progress report dated April 7, 2015 from a representative for CHS, swing beds have not been initiated due to difficulties in recruiting and retaining qualified therapy support for these patients. It was projected the service will be initiated by October 1, 2015. 10/7/2015-An update from a representative of CHS indicates CHS is in the process of evaluating the financial feasibility of the project. A decision will be made by CHS by January 31, 2016.*

North Knoxville Medical Center f/k/a Mercy Medical Center-North, CN1106-019A, has an outstanding Certificate of Need that will expire on 12/1/2015. The CON was approved at the October 26, 2011 Agency meeting for acquisition of a second linear accelerator for its radiation therapy department located on Mercy Medical Center-North campus located at 7551 Dannaher Way, Powell (Knox County), Tennessee 37849. The estimated project cost is **\$4,694,671**. *Project Status Update: Per an annual progress report dated July 30, 2015 from a representative for North Knoxville Medical Center, Health Management Associates was purchased by Community Health Systems ("CHS"). CHS took ownership of the former Health Management hospitals, including North Knoxville Medical Center and the other Tennova Healthcare hospitals, on January 27, 2014. During the transition period*

TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER

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leading up to the ownership change, all capital projects were put on hold by Health Management. The project was reevaluated by CHS considering the reopening of the Baker Cancer Center and the future impact of the relocation of Physicians Regional Medical Center to its new location. The project and its funding have since been approved by Community Health Systems. Construction is scheduled to begin on October 26, 2015 with an estimated construction completion date of March 30, 2016. The Purchase and License agreements have been completed for the Equipment, installation, licensing, training and support. North Knoxville Medical Center anticipates the project will not be completed until April 2016, and will therefore be requesting a one year extension for this project, prior to the CON expiration date.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, denied or pending applications, or outstanding Certificate of Needs for other health care organizations in the service area proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME
(10/07/2015)

LETTER OF INTENT



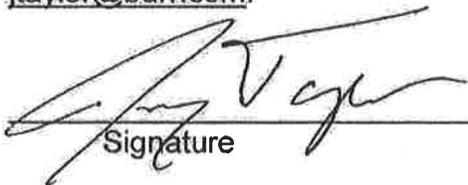
**LETTER OF INTENT
TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY**

The Publication of Intent is to be published in the Knoxville News Sentinel, which is a newspaper of general circulation in Campbell County, Tennessee, on or before August 9, 2015 for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that Tennova Healthcare -- LaFollette Medical Center, owned and managed by Campbell County HMA, LLC, a Tennessee limited liability company, intends to file an application for a Certificate of Need for the initiation of extracorporeal shockwave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus located at 923 East Central Avenue, LaFollette, Campbell County Tennessee. Tennova Healthcare -- LaFollette Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Health Care Facilities. This project involves no change in the number or types of licensed inpatient beds. The estimated project cost is not to exceed \$850,000.

The anticipated date of filing the application is August 14, 2015.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Burr & Forman, LLP, 511 Union Street, Suite 2300, Nashville, Tennessee 37219, 615-724-3247, jtaylor@burr.com.



Signature

8-7-15

Date

=====
The published Letter of Intent contains the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.
=====

COPY

TENNOVA Healthcare

LaFollette Medical

Center (Lithotripsy)

CN1508-032

CERTIFICATE OF NEED APPLICATION

FOR

**TENNOVA HEALTHCARE -
LAFOLLETTE MEDICAL CENTER**

Initiation of Part-Time Lithotripsy Service

Campbell County, Tennessee

August 14, 2015

Contact Person:

**Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247**

00240101000

SECTION A:

APPLICANT PROFILE

1.	<u>Name of Facility, Agency, or Institution</u>		
	Campbell County HMA, LLC, d/b/a Tennova Healthcare--LaFollette Medical Center		
	Name		
	923 Central Avenue		Campbell
	Street or Route		County
	LaFollette	TN	37762
	City	State	Zip Code
2.	<u>Contact Person Available for Responses to Questions</u>		
	Jerry W. Taylor	Attorney	
	Name	Title	
	Burr & Forman, LLP	jtaylor@burr.com	
	Company Name	Email address	
	501 Union Street, Suite 2300	Nashville TN	37219
	Street or Route	City	State
	Attorney	615-724-3247	615-724-3347
	Association with Owner	Phone Number	Fax Number
3.	<u>Owner of the Facility, Agency or Institution</u>		
	Campbell County HMA, LLC	423-907-1200	
	Name	Phone Number	
	c/o Tennova Healthcare --LaFollette Medical Center (see above)	Campbell	
	Street or Route	County	
	LaFollette	TN	37762
	City	State	Zip Code
4.	<u>Type of Ownership of Control (Check One)</u>		
	A. Sole Proprietorship	F. Government (State of TN or	
	B. Partnership	G. Political Subdivision)	
	C. Limited Partnership	H. Joint Venture	
	D. Corporation (For Profit)	I. Limited Liability Company	X
	E. Corporation (Not-for-Profit)	Other (Specify)_____	

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

Organizational documentation is attached as Attachment A, 4.

5. Name of Management/Operating Entity (If Applicable) N/A

Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. Legal Interest in the Site of the Institution (Check One)

- A. Ownership
- B. Option to Purchase
- C. Lease of 10 Years (Initial term) X
- D. Option to Lease
- E. Other (Specify) _____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

A copy of the Lease Agreement and Assignment Agreement is attached as Attachment A, 6.

7. Type of Institution (Check as appropriate--more than one response may apply)

- A. Hospital (Specify) General X
- B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty
- C. ASTC, Single Specialty
- D. Home Health Agency
- E. Hospice
- F. Mental Health Hospital
- G. Mental Health Residential Treatment Facility
- H. Mental Retardation Institutional Habilitation Facility (ICF/MR)
- I. Nursing Home
- J. Outpatient Diagnostic Center
- K. Recuperation Center
- L. Rehabilitation Facility
- M. Residential Hospice
- N. Non-Residential Methadone Facility
- O. Birthing Center
- P. Other Outpatient Facility
- Q. (Specify) _____
- Other (Specify) _____

8. Purpose of Review (Check) as appropriate--more than one response may apply)

- | | | | |
|-----------------------------------|---|--------------------------------------|-------|
| A. New Institution | | G. Change in Bed Complement | |
| B. Replacement/Existing Facility | | [Please note the type of change by | |
| C. Modification/Existing Facility | | <u>underlining the appropriate</u> | |
| D. Initiation of Health Care | X | <i>response: Increase, Decrease,</i> | |
| Service as defined in TCA § | | <i>Designation, Distribution,</i> | |
| 68-11-1607(4) (Specify) | | <i>Conversion, Relocation]</i> | |
| <u>Lithotripsy</u> | | H. Change of Location | _____ |
| E. Discontinuance of OB Services | | I. Other (Specify)_____ | _____ |
| F. Acquisition of Equipment | | _____ | _____ |

[THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

	<u>Current Beds</u>	<u>Licensed *CON</u>	<u>Staffed</u>	<u>Beds</u>	<u>TOTAL</u>
			<u>Beds</u>	<u>Proposed</u>	<u>Beds at</u>
					<u>Completion</u>
A. Medical/Surgical	50	_____	50	_____	50
B. Surgical (included in above)	_____	_____	_____	_____	_____
C. Long-Term Care Hospital	_____	_____	_____	_____	_____
D. Obstetrical	_____	_____	_____	_____	_____
E. ICU/CCU	6	_____	6	_____	6
F. Neonatal	_____	_____	_____	_____	_____
G. Pediatric	_____	_____	_____	_____	_____
H. Adult Psychiatric	_____	_____	_____	_____	_____
I. Geriatric Psychiatric	10	_____	10	_____	10
J. Child/Adolescent Psychiatric	_____	_____	_____	_____	_____
K. Rehabilitation	_____	_____	_____	_____	_____
L. Nursing Facility (non-Medicaid Certified)	_____	_____	_____	_____	_____
M. Nursing Facility Level 1 (Medicaid only)	_____	_____	_____	_____	_____
N. Nursing Facility Level 2 (Medicare only)	_____	_____	_____	_____	_____
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	_____	_____	_____	_____	_____
P. ICF/MR	_____	_____	_____	_____	_____
Q. Adult Chemical Dependency	_____	_____	_____	_____	_____
R. Child and Adolescent Chemical Dependency	_____	_____	_____	_____	_____
S. Swing Beds	_____	_____	_____	_____	_____
T. Mental Health Residential Treatment	_____	_____	_____	_____	_____
U. Residential Hospice	_____	_____	_____	_____	_____
TOTAL	66	_____	66	_____	66

10. **Medicare Provider Number:** 440033
Certification Type: Hospital

11. **Medicaid Provider Number:** 0440033
Certification Type: Hospital

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**

Tennova Healthcare Lafollette Medical Center is certified for both programs.

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.**

AMERIGROUP

BlueCare

UnitedHealthcare Community Plan

TennCare Select

Will this project involve the treatment of TennCare participants?

Yes

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

The applicant is contracted with of the TennCare MCOs operating in the area.

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

N/A

NOTE: *Section B* is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. *Section C* addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Project Description

The applicant, Campbell County HMA, LLC, d/b/a Tennova Healthcare -- LaFollette Medical Center (hereafter "TH-LMC") proposes to initiate extracorporeal shockwave lithotripsy ("ESWL" or "lithotripsy") services up to three days per week through the use of a leased mobile lithotripsy unit. The applicant seeks authorization for up to three days per week. The services will be provided in existing space on the TH-LMC campus. There is no construction or renovation involved in this project.

Services & Equipment

Services to be provided are lithotripsy treatments. The equipment is a HealthTronics LithoDiamond Multifunctional Lithotripsy System.

Ownership Structure

The owner of the hospital is Campbell County, HMA, LLC. It is affiliated through several subsidiaries with Community Health Systems, Inc. An organizational chart of the ownership is attached as Attachment B, I.

Service Area

The proposed service area consists of Campbell, Claiborne and Scott counties. Residents of these three counties accounted for 89% of admissions at TH-LMC in 2013.

Need

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Until recently, TH-LMC did not have an urologist on its medical staff. In August, 2015 Dr. Sean DeLair, a board certified Urologist, relocated his practice from Kentucky to LaFollette. Dr.

DeLair is trained and has significant experience in delivering lithotripsy treatments. He knows from experience there is a need for lithotripsy services in rural communities so patients do not have to travel to urban areas to receive needed treatment.

A significant number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Between 2013-2015 the number of such E.D. visits averaged 358 patients per year. Not all of these are kidney stone cases or candidates for lithotripsy, but some undoubtedly are, and this further supports the need for the lithotripsy service at TH-LMC.

Prior to Dr. DeLair's arrival at TH-LMC, these patients could not be treated at the hospital. Now that Dr. DeLair is on the medical staff, lithotripsy services can be offered at TH-LMC, providing local access to needed care for service area residents.

Existing Resources

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Project Cost & Funding

The project cost is \$437,203, exclusive of the filing fee. The project will be funded through operating revenues, or, if necessary, the cash reserves of CHS / Community Health Systems, Inc.

Financial Feasibility

The project is financially feasible. It will be profitable in its first year of operation and thereafter. There are no capital expenditures required.

Staffing

Staffing will include a RN, a surgical tech, a CRNA, and a radiological technologist, all on a part-time basis. The radiological technologist is supplied by the mobile vendor. The applicant will not have to increase its staff for this project.

- II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.**
- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new**

construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

N/A. No construction or renovation is involved in this project.

If the project involves none of the above, describe the development of the proposal.

The mobile lithotripsy unit is easily moved on attached wheels from place to place as needed. The unit is lightweight and compact. Most days it will be located in the cystology procedure room located in the surgery department. If for some reason the cystology room is not available, the lithotripsy can be used in either of the two operating rooms in the department.

- B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.**

N/A.

- C. **As the applicant, describe your need to provide the following health care services (if applicable to this application):**

Extracorporeal Lithotripsy:

There is no lithotripsy unit located in the 3 county service area. The closest units are located approximately 45 minutes' to one hour drive time in Knox County and Anderson County.

Until recently, TH-LMC did not have an urologist on its medical staff. In August, 2015 Dr. Sean DeLair, a board certified Urologist, relocated his practice from Kentucky to LaFollette. Dr. DeLair is trained and has significant experience in delivering lithotripsy treatments. He knows from experience there is a need for lithotripsy services in rural communities so patients do not have to travel to urban areas to receive needed treatment.

A significant number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Between 2013-2015 the number of such E.D. visits averaged 358 patients per year. Not all of these are kidney stone cases or candidates for lithotripsy, but some undoubtedly are, and this further supports the need for the lithotripsy service at TH-LMC.

Prior to Dr. DeLair's arrival at TH-LMC, these patients could not be treated at the hospital. Now that Dr. DeLair is on the medical staff, lithotripsy services can be offered at TH-LMC, providing local access to needed care for service area residents.

- D. **Describe the need to change location or replace an existing facility.**

N/A

- E. **Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$2 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:**

1. **For fixed-site major medical equipment (not replacing existing equipment):**

N/A.

- a. **Describe the new equipment, including:**

1. **Total cost (As defined by Agency Rule).**
2. **Expected useful life;**
3. **List of clinical applications to be provided; and**

4. Documentation of FDA approval.

- b. Provide current and proposed schedules of operations.**

2. For mobile major medical equipment:

- a. List all sites that will be served;**

During the applicant's leased time, the unit will be located on the hospital campus.

- b. Provide current and/or proposed schedule of operations;**

The exact days the unit will be used have not been determined. Initially, the applicant plans on operating the service one day per week, until volume grows to a level justifying additional days. On the days it is on site, it will operate between the hours necessary to provide all scheduled treatments.

- c. Provide the lease or contract cost.**

The total of the lease payments in Year 1 (initial term of the lease) is \$396,000.

- d. Provide the fair market value of the equipment; and**

The estimated FMV of the lithotripsy unit is \$120,000 (estimated purchase price from vendor, \$200,000, x 60% representing 3 days part-time use).

A letter from HealthTronics stating the estimated value of the equipment is attached as Attachment B, II, 2.

- e. List the owner for the equipment.**

Kentucky 1 Lithotripsy, a subsidiary of HealthTronics, Inc.

- 3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.**

The equipment will be leased on a part time basis from Kentucky 1 Lithotripsy pursuant to a Mobile Lithotripsy Services Agreement. Under the Agreement, the owner provides the lithotripsy unit and one radiologic technologist. The hospital provides space for the unit, a supervising urologist, a CRNA, and any needed supplies and medications. The payment from the hospital to Kentucky 1 is \$2,400 per treatment. The initial term of the agreement is one year.

A copy of the Mobile Lithotripsy Services Agreement is attached as Attachment B, II, 3.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. Size of site (*in acres*);
2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

Two plot plans are attached: (1) a Title Survey map which is not ideally legible but is all that is available, and (2) an aerial shot from Google Earth. These are attached as Attachment B, III.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

There is no public transportation service in LaFollette. The hospital is located on Central Avenue, which is a four lane highway and a major thoroughfare in the area. The hospital is easily accessible for patients and the public.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: DO NOT SUBMIT BLUEPRINTS. Simple line drawings should be submitted and need not be drawn to scale.

A floor plan drawing of the area of the hospital where the lithotripsy unit will be located is attached as Attachment B, IV.

V. For a Home Health Agency or Hospice, identify:

N/A.

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), “no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care.” The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2” x 11” white paper.* All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate “Not Applicable (NA).”

QUESTIONS

I. NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee’s Health: Guidelines for Growth.

Five Principles for Achieving Better Health from the Tennessee State Health Plan:

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person’s health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

This appears to be a policy statement to which no response is necessary.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

The proposed lithotripsy service would be the only such service in the 3 county service area. It will improve access to health care for the service area population.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

This project involves no capital expense. It will be funded through operating revenues of the lithotripsy service.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

TH-LMC is accredited by the Joint Commission and is in good standing with both the TJC and the Tennessee Departmental Health. Lithotripsy is a very safe, non-invasive treatment.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

This project does not require any additional hospital staffing, and should have no impact on the local workforce.

- a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY

1. Determination of Need: The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + 0$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

0 = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

These calculations have been performed by the Department of Health for all counties in Tennessee. The results are attached as Attachment C, I, Need, 1 (1).

For the 3 county service area the calculations reflect a need for 128 treatments in 2018.

2. Minimum Volume Standard: Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

TH-LMC seeks authorization to operate the lithotripsy service for up to 3 days per week. The pro-rated minimum volume is 150 treatments (3/5 of 250). The applicant is projecting 165 lithotripsy treatments in Year 1.

3. Current Service Area Utilization: The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

N/A. There are no existing providers of lithotripsy service in the service area.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

The Department of Health has prepared such a report, and it is attached as Attachment C, I, Need, 1 (2). This report shows that 148 residents of the eservice area received lithotripsy services in 2013. This is 20 more treatments than the calculated "need" for 2018.

4. Adverse Impact on Existing Providers: An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

N/A. There are no existing providers of lithotripsy service in the service area.

5. Adequate Staffing and Services: The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:

a. The existence of an active radiology service and an established referral urological practice;

A board certified urologist, Dr. Sean DeLair, has recently joined the TH-LMC medical staff after relocating his practice from Somerset, Kentucky. A letter from Dr. DeLair is attached as Attachment C, I, Need, 1 (3).

Also included in the referenced attachment is a letter from Dr. Jan Robbins, Chief of the Medical Staff and Medical Director of the E.D. Dr. Robbins attests to the need for a local lithotripsy service, and states that approximately 30 patients per month are diagnosed with kidney stones in the TH-LMC emergency department. Letters from other physicians who work in the E.D are also included.

Also included in the referenced attachment are letters from numerous physicians in the area, including internists and family practitioners. These physicians are typically referral sources for patients needing lithotripsy. All attest to the need for a local lithotripsy service.

b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and

University of Tennessee Medical Center in Knox County is 48 minutes' drive time from TH-LMC.

Oak Ridge Medical Center in Anderson County is 49 minutes' drive time from TH-LMC.

Source: Google Maps

c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

Dr. DeLair, who is currently the only urologist who will be the attending physician for the lithotripsy program, is board certified in Urology.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

The radiologic technologist trained in ESWL is provided by the equipment vendor. Under the Mobile Lithotripsy Services Agreement, the vendor is obligated to assure the technologist is properly trained and certified.

6. ESWL Equipment: Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

A copy of the FDA approval documentation is attached as Attachment C, I, Need, 1 (4).

7. Quality Control and Monitoring: The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

The Mobile Lithotripsy Services Agreement provides for a cooperative Quality Assurance program between the mobile vendor and the hospital. Section 4 provides the mobile vendor has the following relevant responsibilities:

"e. Creating and maintaining a quality assurance program for monitoring and improving the efficacy of the operation of the ESL and the ESL Services provided by Provider on Hospital premises, and complying with all applicable standards of The Joint Commission (TJC) and Medicare standards, including the applicable Medicare conditions of participation for hospital contracted services currently specified at 42 CFR 482.12(e). Provider shall cooperate with Hospital's quality assurance committee in its periodic review, on a random sample basis, of services provided to Hospital patients by Provider pursuant to the terms of this Agreement. Quality assurance reports may be requested by mailing the request to the address as indicated below. Quality assurance reports will include quality assurance activities conducted;

* * *

g. At Hospital's request, participate in Hospital's utilization review program and any other Hospital program or committee with respect to the ESL Services that would be required if the ESL services were furnished directly by the Hospital. Furthermore, Provider shall meet with Hospital management as appropriate and necessary on a periodic basis to discuss pertinent issues relating to the arrangement and/or ESL services;"

A sample QA Report, referenced in sub-section (e) above is attached as Attachment C, I, Need, 1 (5).

8. Data Requirements: Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees.

9. Transfer and/or Affiliation Agreements: If an applicant is not a designated Level I trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

TH-LMC has a transfer agreement with University of Tennessee Medical Center, a Level I Trauma Center. A copy is attached as Attachment C, I, Need, 1, (6).

10. Access: In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All 3 counties in the service area are designated as Medically Underserved Areas by the HRSA. Documentation is attached as Attachment C, I, Need, 1, (7).

b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

All 3 counties in the service area have a higher lithotripsy use rate than that of the state as a whole:

<u>County</u>	<u>County Use Rate</u>	<u>Statewide Use Rate</u>
Campbell	.0019445	.0012927
Claiborne	.0023640	.0012927
Scott	.0015612	.0012927

This in part explains the fact that in 2013 more service area residents received lithotripsy treatments (148) than the calculated "need" for 2018 (128), the latter of which is based on the statewide use rate.

c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

TH-LMC does receive Essential Access Program payments.

[End of responses to State Health Plan]

- b. **Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)**

N/A.

2. **Describe the relationship of this project to the applicant facility's long-range development plans, if any.**

The proposed lithotripsy service is not related to any other long range plans of TH-LMC.

3. **Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11"**

The proposed service area consists of Campbell, Claiborne and Scott counties. Residents of these three counties accounted for 89% of admissions at TH-LMC in 2013.

A map of the service area is attached as Attachment C, I, Need, 3.

4. **A. Describe the demographics of the population to be served by this proposal.**

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

A Population and Demographics Table is attached as Attachment C, I, Need, 4.

5. **Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.**

N/A. There are no existing providers of lithotripsy service in the service area.

6. **Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology**

must include detailed calculations or documentation from referral sources, and identification of all assumptions.

This is a proposed new service, so there is no applicable historical utilization data.

It should be noted, however, that a high number of patients present at the TH-LMC emergency department who are discharged with a diagnosis of "Possible Urology." Since until recently TH-LMC did not have an urologist on staff, these patients could not be treated.

<u>Year:</u>	<u>"Possible Urology" Diagnosed Cases:</u>
2013	410
2014	347
2015 (Annualized 7-31)	317

Of course not all of these are kidney stone cases or candidates for lithotripsy, but some portion are and it further supports the need for the lithotripsy service at TH-LMC.

Projected Utilization:

Year 1: 165 treatments

Year 2: 180 treatments

These are reasonable projections based on the following considerations and assumptions:

1. According to outmigration data provided by the Department of Health, 148 service area residents received lithotripsy treatments in 2013.
2. An average of 358 patients per year presented at the TH-LMC emergency department and were discharged with a "Possible Urology" diagnosis between 2013-2015. While not all of these are kidney stone cases or candidates for lithotripsy some are, and this indicates the need for treatments may be higher than the 148 treatments received in 2013.
3. Letters from local physicians, including internists and family medicine physicians, who are referral sources for lithotripsy patients, indicate a need for a local lithotripsy service. Although the numbers of such potential referrals was not quantified, this physician support confirms the need for the lithotripsy service at TH-LMC.

4. All service area counties have a higher lithotripsy use rate than does the state as a whole.

5. Although the "need" for 2018 lithotripsy based on the statewide use rate is 128 treatments, the reliability of this statistic is undermined by the fact that 148 patients from the service area actually received such treatment in 2013.

6. The absence of a locally available lithotripsy service may cause the number of service area residents who receive the service to be lower than it would be if a local service was available. This would be patients who need the service but who are unable or unwilling to leave the service area to receive it.

II. ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

- All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
- The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.

For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

A completed Project Cost Chart is attached on the following page.

PROJECT COSTS CHART

AUG 14 '15 02:57

A.	Construction and equipment acquired by purchase:		
	1. Architectural and Engineering Fees	_____	
	2. Legal, Administrative, Consultant Fees	\$ _____	30,000
	3. Acquisition of Site	_____	
	4. Preparation of Site	_____	
	5. Construction Costs	_____	
	6. Contingency Fund	_____	
	7. Fixed Equipment (Not included in Construction Contract)	_____	
	8. Moveable Equipment (List all equipment over \$50,000.00)	_____	
	9. Other (Specify) _____	_____	
B.	Acquisition by gift donation, or lease:		
	1. Facility (Inclusive of building and land)	_____	
	2. Building Only	_____	
	3. Land Only	_____	
	4. Equipment (Specify) <u>Lithotripsy Unit (\$2,400/procedure)</u>	\$ _____	396,000.00
	5. Other (Specify) <u>Supplies and Medications</u>	\$ _____	11,203.00
C.	Financing Costs and Fees:		
	1. Interim Financing	_____	
	2. Underwriting Costs	_____	
	3. Reserve for One Year's Debt Service	_____	
	4. Other (Specify) _____	_____	
D.	Estimated Project Cost (A+B+C)	\$ _____	437,203.00
E.	CON Filing Fee	\$ _____	3,000.00
F.	Total Estimated Project Cost (D & E)	\$ _____	440,203.00
	TOTAL	\$ _____	440,203.00

2. Identify the funding sources for this project.

a. Please check the applicable item(s) below and briefly summarize how the project will be financed. (*Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.*)

- A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
 - B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
 - C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
 - D. Grants--Notification of intent form for grant application or notice of grant award; or
 - E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- No out-of pocket capital outlay is required. This project will almost certainly be funded through operating revenues of the lithotripsy service. However, if and to the extent a capital outlay is required, a funding letter is attached as Attachment C, II, Economic Feasibility, 2.
- F. Other—Identify and document funding from all other sources.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

4. Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

Attached on the following pages are:

1. A Historical data Chart for the entire hospital
2. A projected Data Chart for the entire hospital.
3. A Projected Data Chart for the Lithotripsy service.

HISTORICAL DATA CHART

AUG 15 2015

Give information for the last three (3) years for which complete data are available for the facility or agency.

	2012	2013	2014
A. Utilization/Occupancy Data: Admissions	2359	2586	2416
B. Revenue from Services to Patients			
1. Inpatient Services	\$50,801,155	\$64,614,690	\$ 68,585,717
2. Outpatient Services * ER services included in Outpatient	\$181,833,261	\$167,394,260	\$ 169,161,849
3. Emergency Services			
4. Other Operating Revenue	\$175,961	\$140,165	\$ 148,430
Specify: <u>rental income, etc.</u>			
Gross Operating Revenue	\$232,810,377	\$232,149,115	\$ 237,895,996
C. Deductions from Operating Revenue			
1. Contract Deductions	\$153,746,090	\$161,451,618	\$ 168,614,728
2. Provision for Charity Care	\$8,316,056	\$8,820,398	\$ 8,729,992
3. Provision for Bad Debt	\$6,449,325	\$5,215,629	\$ 6,710,067
Total Deductions	\$168,511,471	\$175,487,645	\$ 184,054,787
NET OPERATING REVENUE	\$64,298,906	\$56,661,470	\$ 53,841,209
D. Operating Expenses			
1. Salaries and Wages	\$14,713,218	\$14,263,599	\$ 14,021,991
2. Physicians' Salaries and Wages			
3. Supplies	\$15,214,172	\$12,600,913	\$ 13,099,986
4. Taxes	\$588,379	\$553,777	\$ 551,740
5. Depreciation	\$4,020,203	\$4,401,153	\$ 4,085,725
6. Rent	\$1,041,434	\$1,000,469	\$ 650,482
7. Interest, other than Capital			
8. Management Fees:			
a. Fees to Affiliates	\$10,632,434	\$3,380,664	\$ 1,401,537
b. Fees to Non-Affiliates			
9. Other Expenses	\$12,480,266	\$13,038,487	\$ 12,515,816
Specify: <u>benefits, profees, outside svcs, maint, etc.</u>			
Total Operating Expenses	\$58,690,106	\$49,239,062	\$ 46,327,277
E. Other Revenue (Expenses)--Net			
Specify: _____			
NET OPERATING INCOME (LOSS)	\$5,608,800	\$7,422,408	\$ 7,513,932
F. Capital Expenditures			
1. Retirement of Principal			
2. Interest			
Total Capital Expenditures	\$0	\$0	\$ -
NET OPERATING INCOME (LOSS)	\$5,608,800	\$7,422,408	\$ 7,513,932
LESS CAPITAL EXPENDITURES	\$0	\$0	\$ -
NOI LESS CAPITAL EXPENDITURES	\$5,608,800	\$7,422,408	\$ 7,513,932

historical

Other Expenses

	2012	2013	2014
benefits	3,825,998	3,865,505	4,244,916
prof. fees	546,020	210,526	201,380
outside services	3,172,182	4,073,050	4,767,219
repairs & maint	942,258	921,197	1,083,417
utilities	640,100	497,936	675,950
general insurance	845,567	604,917	740,404
other taxes	1,862,919	1,848,149	1,918,012
property tax	254,771	227,434	270,820
sales tax	333,608	326,344	191,357
other	56,844	463,429	31,549
Hitech Incentive			-1609208
	12,480,266	13,038,487	12,515,815

Other Revenue

	2012	2013	2014
OTHER REVENUE	15,440	15,654	16,577
CAFETERIA SALES	332		
GIFT SHOP SALES	14,837	3562.18	3,772
VENDING SALES	6,463	12576.15	13,318
COT RENTAL			
OTHER RENTAL	111,649	99382.95	105,243
MEDICAL TRANS.	738	620.05	657
INTEREST INCOME	1,663	-2143.1	-2,269
MISCELLANEOUS INCC	24,836	10512.89	11,133
SUPPLIES SOLD	4		
	175,961	140,165	148,430

PROJECTED DATA CHART (Whole Hospital)

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

	Year 1	Year 2
A. Utilization/Occupancy Data (Admissions).	2,464	2,514
B. Revenue from Services to Patients		
1. Inpatient Services	\$ 69,957,431	\$ 71,356,580
2. Outpatient Services	\$ 174,085,793	\$ 179,308,367
3. Emergency Services	\$ -	\$ -
4. Other Operating Revenue (Specify) _____	\$ 148,430	\$ 151,399
Gross Operating Revenue	\$ 244,191,655	\$ 250,816,346
C. Deductions from Operating Revenue		
1. Contractual Adjustments	\$ 173,253,880	\$ 177,957,062
2. Provisions for Charity Care	\$ 8,959,603	\$ 9,202,822
3. Provisions for Bad Debt	\$ 6,682,202	\$ 6,863,605
Total Deductions	\$ 188,895,684	\$ 194,023,490
NET OPERATING REVENUE	\$ 55,295,971	\$ 56,792,856
D. Operating Expenses		
1. Salaries and Wages	\$ 14,305,916	\$ 14,595,837
2. Physicians' Salaries and Wages		
3. Supplies	\$ 13,236,121	\$ 13,506,132
4. Taxes	\$ 551,740	\$ 551,740
5. Depreciation	\$ 4,085,725	\$ 4,085,725
6. Rent	\$ 650,482	\$ 650,482
7. Interest, other than Capital		
8. Management Fees:		
a. Fees to Affiliates	\$ 1,401,537	\$ 1,401,537
b. Fees to Non-Affiliates		
9. Other Expenses	\$ 12,911,816	\$ 12,923,696
Specify: _____		
Total Operating Expenses	\$ 47,143,337	\$ 47,715,149
E. Other Revenue (Expenses)--Net		
Specify: _____		
NET OPERATING INCOME (LOSS)	\$ 8,152,633	\$ 9,077,707
F. Capital Expenditures		
1. Retirement of Principal		
2. Interest		
Total Capital Expenditures	\$ -	\$ -
NET OPERATING INCOME (LOSS)	\$ 8,152,633	\$ 9,077,707
LESS CAPITAL EXPENDITURES	\$ -	\$ -
NOI LESS CAPITAL EXPENDITURES	\$ 8,152,633	\$ 9,077,707

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PDC Whole Hospital	Other Expenses	
	year 1	year 2
benefits	4,244,916	4,244,916
prof. fees	201,380	201,380
purchased services	5,163,219	5,163,219
repairs & maint	1,083,417	1,083,417
utilities	675,950	675,950
general insurance	740,404	740,404
other taxes	1,918,012	1,918,012
property tax	270,820	270,820
sales tax	191,357	191,357
marketing, travel, etc.	31,549	31,549
Hitech Incentive	-1,609,208	-1,609,208
	12,911,815	12,911,815

	Other Revenue	
	year 1	year 2
MEDICAID SETTLEMENT	\$ 16,576.83	\$ 16,908.36
GIFT SHOP SALES	\$ 3,772.23	\$ 3,847.68
VENDING	\$ 13,317.73	\$ 13,584.08
OTHER RENTAL INCOME	\$ 105,243.27	\$ 107,348.13
MEDICAL TRANSCRIPTS	\$ 656.61	\$ 669.74
INTEREST INCOME	\$ (2,269.47)	\$ (2,314.86)
MISC. REFUNDS & REBATES	\$ 11,132.80	\$ 11,355.46
	148,430	151,399

August 31, 2015**PROJECTED DATA CHART REVISED (Lithotripsy Only) 8:49 am**

Give information for the two (2) years following completion of this proposal. The fiscal year begins in _____.

	Year 1	Year 2
A. Utilization/Occupancy Data (Specify unit of measure).	165	180
B. Revenue from Services to Patients		
1. Inpatient Services		\$ -
2. Outpatient Services	\$ 1,540,704.00	\$ 1,680,768.00
3. Emergency Services	\$ -	\$ -
4. Other Operating Revenue (Specify) _____		\$ -
Gross Operating Revenue	\$ 1,540,704.00	\$ 1,680,768.00
C. Deductions from Operating Revenue		
1. Contractual Adjustments	\$ 941,051.84	\$ 1,026,602.01
2. Provisions for Charity Care	\$ 48,722.76	\$ 53,152.10
3. Provisions for Bad Debt	\$ 37,449.40	\$ 40,853.89
Total Deductions	\$ 1,027,224.00	\$ 1,120,608.00
NET OPERATING REVENUE	\$ 513,480.00	\$ 560,160.00
D. Operating Expenses		
1. Salaries and Wages	\$ 18,067.50	\$ 19,710.00
2. Physicians' Salaries and Wages		
3. Supplies	\$ 5,134.80	\$ 5,601.60
4. Taxes		
5. Depreciation		
6. Rent		
7. Interest, other than Capital		
8. Management Fees:		
a. Fees to Affiliates		
b. Fees to Non-Affiliates		
9. Other Expenses	\$ 396,000.00	\$ 432,000.00
Specify: _____		
Total Operating Expenses	\$ 419,202.30	\$ 457,311.60
E. Other Revenue (Expenses)--Net		
Specify: _____		
NET OPERATING INCOME (LOSS)	\$ 94,277.70	\$ 102,848.40
F. Capital Expenditures		
1. Retirement of Principal		
2. Interest		
Total Capital Expenditures	\$ -	\$ -
NET OPERATING INCOME (LOSS)	\$ 94,277.70	\$ 102,848.40
LESS CAPITAL EXPENDITURES	\$ -	\$ -
NOI LESS CAPITAL EXPENDITURES	\$ 94,277.70	\$ 102,848.40

Projected Data Chart (Lithotripsy Only)

Other Expenses:

Year 1

Year 2

Mobile Lithotripsy Lease Payments:

\$396,000

\$432,000

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Average Gross Charge:	\$9,337.61
Average Deduction:	\$6,225.61
Average Net Charge:	\$3112.00

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

This is a proposed new service, so there are no current charges. The proposed charges are:

Description	HCPCS	Net Charge	Gross Charge
LITHOTRIPSY UNILATERAL	50590	\$3,112.54	\$9,337.62
BILATERAL LITHOTRIPSY	50590	\$3,112.54	\$9,337.62

This proposal will not impact existing patient charges.

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

There are no lithotripsy providers in the service area. Charges for lithotripsy services in any adjoining areas are not available to the applicant. To the applicant's knowledge no new lithotripsy services have been approved recently enough that the comparison would be meaningful.

Below are the average gross charges per procedure for lithotripsy treatments, from the HSDA Medical Equipment Registry.

Equipment Type	1st Quartile	Median	3rd Quartile
Lithotripter	\$9,029.86	\$12,783.82	\$17,953.48

Source: HSDA Medical Equipment Registry - 1/7/2015

7. **Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

As reflected on the Projected Data Chart, the proposal is profitable in Year and thereafter.

8. **Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.**

As reflected in the Projected Data Chart, financial viability will be achieved in Year 1.

9. **Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.**

TH-LMC participates in the Medicare and TennCare programs. It contracts with all TennCare networks operating in the region. The estimated revenues and payor mixes for the lithotripsy program are reflected below:

<u>Payor</u>	<u>Payor Mix</u>	<u>Net Revenue Year 1</u>
Medicare:	59.5%	\$305,521
TennCare:	17.6%	\$90,372

10. **Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.**

The financials for TH-LMC are rolled up into the Consolidated financials of the parent company. A copy of the audited Consolidated Statements of Income and Consolidated Balance Sheets for Community Health Systems, Inc. and Subsidiaries is attached as Attachment C, II, Economic Feasibility 10.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

No more cost effective alternatives were identified. The leased, part-time lithotripsy service arrangement calls for a fixed payment per procedure by the hospital to the mobile vendor. The hospital then bills the 3rd party payor. No construction or renovation of the hospital is required. This proposal require little or no out of pocket capital expenditure, and can be financially sustained through operating revenues of the program. .

- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.**

As mentioned above, the is no construction hospital renovation required. No superior alternatives were identified, or are thought to exist.

(III.) CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

- 1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.**

- Team Health – Emergency Department physician coverage
- Resource Anesthesia – CRNA Coverage Vendor
- Innovative Pathologists – Pathology Vendor
- Abercrombie – Radiology Vendor
- Healogics – Wound Care Vendor
- University of Tennessee Medical Center -- Transfer Agreement
- Kentucky 1 Lithotripsy -- Mobile Lithotripsy Services Agreement

- 2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition**

arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

This proposal will have a positive effect on the health care system. It will bring a needed health care service that is currently not available in the service area.

This proposal will have no negative effect on the health care system. There are no exiting providers of lithotripsy in the service area. No capital expenditure is required, so even if the service were to be utilized at a rate less than the projected volume, there would be no added cost to the health care system.

3. **Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.**

<u>Staffing</u>	<u>Wage</u>	<u>Median Wage (TDLWD)*</u>
1 RN	\$27/hour	\$28.19
1 surgical tech	\$17/hour	\$18.73
1 CRNA	\$250/hour	\$71.08

* Wages are stated as annual salaries on the TDLWD website. Those annual salaries were converted to an hourly rate based on 2,000 annual hours. In some cases the conversion may not result in an accurate hourly rate for part-time contractual services (e.g., the CRNA).

These positions are from the current hospital staff. No new staffing is required.

4. **Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.**

TH-LMC maintains compliance with all applicable regulatory and licensing requirements, including any staffing requirements. This proposal does not call for any additional staffing.

5. **Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing,**

admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

The applicant so verifies.

6. **Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).**

TH-LMC has training affiliations with the following educational institutions:

- Lincoln Memorial University
- South College
- Appalachian College of Pharmacy
- Tennessee Center for Applied Technology
- University of Tennessee
- Kaplan University
- Mercer University
- Anderson County Schools
- King College
- Roane State Community College
- Southeast Kentucky Community & Technology College
- Tennessee State
- Virginia College
- Creighton University
- Brenau University

7. (a) **Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

The applicant so verifies.

- (b) **Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.**

Licensure: Tennessee Board for Licensing Health Care Facilities

Accreditation: The Joint Commission

If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

TH-LMC is in good standing with all licensing and accrediting agencies.

A copy of the hospital license is attached as Attachment C, III, Orderly Development, 7.

- 8. For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.**

Since TH-LMC is Joint Commission accredited, a state licensure survey has not been performed in many years. The applicant could not locate a copy of any state survey.

All deficiencies of the latest TJC survey have been resolved and the Plan of Correction has been accepted. A copy of the most recent TJC survey is attached as Attachment C, III, Orderly Development, 8.

- 9. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.**

There are no settlements, judgments, or final orders entered in any state or country by a licensing agency or court against the professional license held by applicant. Neither CHS / Community Health Systems, Inc. nor Community Health Systems, Inc. holds professional licenses.

- 10. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.**

There are no civil or criminal judgments for fraud or theft against applicant or CHS / Community Health Systems, Inc. which would jeopardize or negatively impact the funding of the project.

- 11. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.**

If the proposal is approved, the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

2015-08-09 15:00:00

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

The Notice of Intent was published in the Knoxville News Sentinel on August 9, 2015. A Publisher's Affidavit will be submitted on or before August 31, 2015.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**

A completed Project Completion Forecast Chart is attached.

- 2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.**

The applicant does not request an extended period of validity at this time.

Form HF0004
 Revised 05/03/04
 Previous Forms are obsolete

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c):
November, 2015

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

<u>Phase</u>	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed	_____	_____
2. Construction documents approved by the Tennessee Department of Health	_____	_____
3. Construction contract signed	_____	_____
4. Building permit secured	_____	_____
5. Site preparation completed	_____	_____
6. Building construction commenced	_____	_____
7. Construction 40% complete	_____	_____
8. Construction 80% complete	_____	_____
9. Construction 100% complete (approved for occupancy)	_____	_____
10. *Issuance of license	N/A	N/A
11. *Initiation of service	30	December, 2015
12. Final Architectural Certification of Payment	_____	_____
13. Final Project Report Form (HF0055)	_____	_____

* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

LIST OF ATTACHMENTS

Organizational documentation	<u>Attachment A, 4</u>
Lease and Assignment	<u>Attachment A, 6</u>
Ownership organizational chart	<u>Attachment B, I</u>
Estimation of Equipment Value	<u>Attachment B, II, 2</u>
Mobile Lithotripsy Services Agreement	<u>Attachment B, II, 3</u>
Site Plans	<u>Attachment B, III</u>
Floor plan	<u>Attachment B, IV</u>
Department of Health need calculations	<u>Attachment C, I, Need, 1 (1)</u>
Department of Health outmigration data	<u>Attachment C, I, Need, 1 (2)</u>
Letter of Support from Attending Urologist	<u>Attachment C, I, Need, 1 (3)</u>
FDA approval documentation	<u>Attachment C, I, Need, 1 (4)</u>
Sample QA Report	<u>Attachment C, I, Need, 1 (5)</u>
Transfer Agreement	<u>Attachment C, I, Need, 1, (6)</u>
HRSA documentation of MUA	<u>Attachment C, I, Need, 1, (7)</u>
Map of the service area	<u>Attachment C, I, Need, 3</u>
Population and Demographics Table	<u>Attachment C, I, Need, 4</u>
Funding Letter	<u>Attachment C, II, Economic Feasibility, 2</u>
Financial Statements	<u>Attachment C, II, Economic Feasibility 10</u>
TJC survey	<u>Attachment C, III, Orderly Development, 8</u>
Hospital license	<u>Attachment C, III, Orderly Development, 7</u>

10/1/2010
 10/1/2010
 10/1/2010



Surveying Division
 State of Tennessee
 Nashville, Tennessee

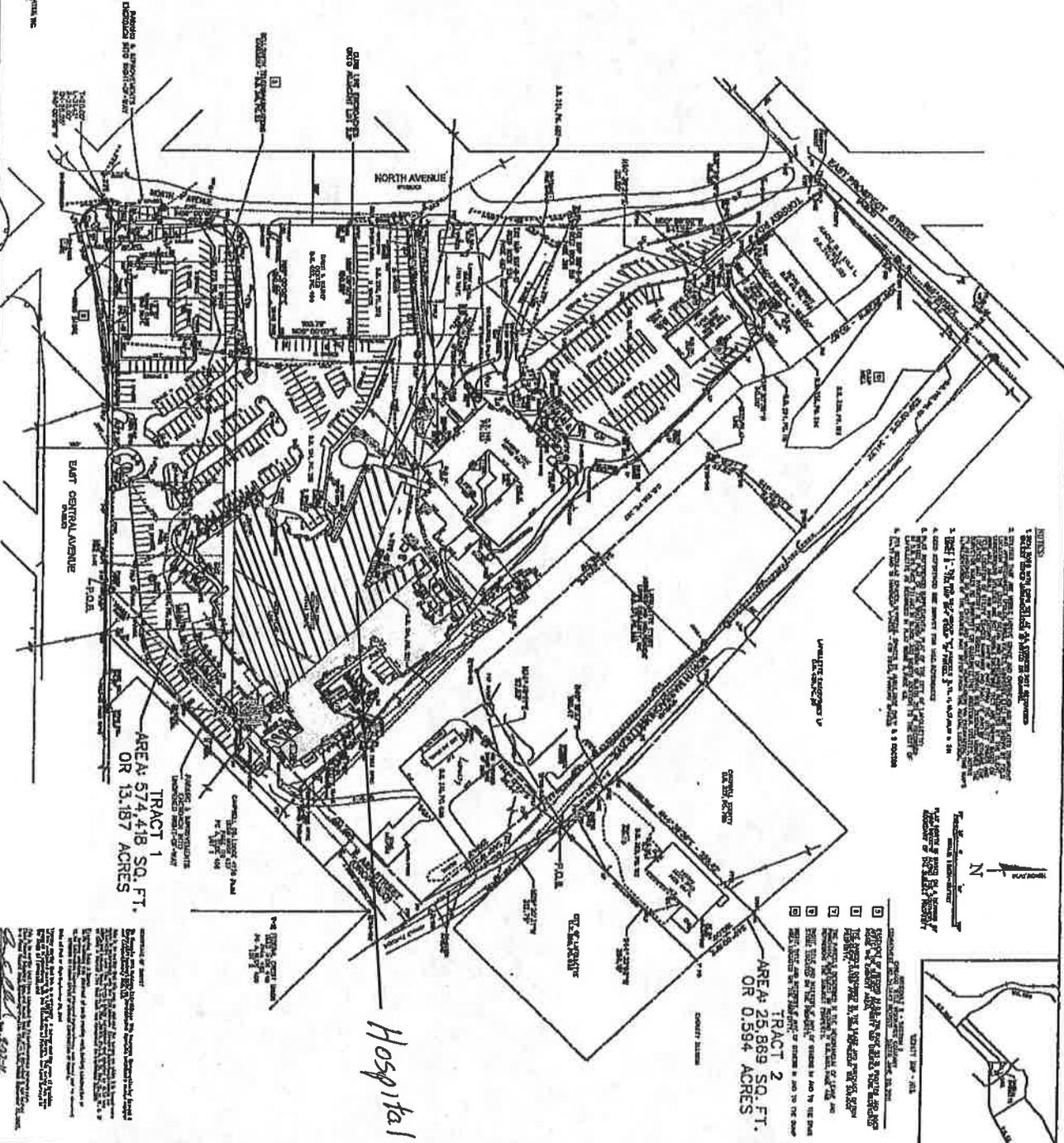
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THIS SURVEY WAS MADE BY ME OR UNDER MY CLOSE PERSONAL SUPERVISION AND TO THE BEST OF MY KNOWLEDGE AND BELIEF IT COMES IN ACCORDANCE WITH THE REQUIREMENTS OF THE SURVEYING ACT OF 1907, AS AMENDED, AND THE RULES AND REGULATIONS OF THE BOARD OF SURVEYING AND MAPPING, STATE OF TENNESSEE.

I, the undersigned, being a duly qualified and licensed Surveyor in the State of Tennessee, do hereby certify that the foregoing is a true and correct copy of the original survey as shown to me by the owner or his agent, and that the same has been compared with the original and found to be a true and correct copy.

Witness my hand and the seal of the State of Tennessee, this 1st day of October, 2010.

 State Surveyor



ALTA/ACSM LAND TITLE SURVEY

823 EAST CENTRAL AVENUE
ST. MARY'S MEDICAL CENTER OF CAMPBELL COUNTY
 1ST CIVIL DISTRICT OF CAMPBELL COUNTY, TENNESSEE - CITY OF LUFKIN, TENNESSEE

1 OF 1

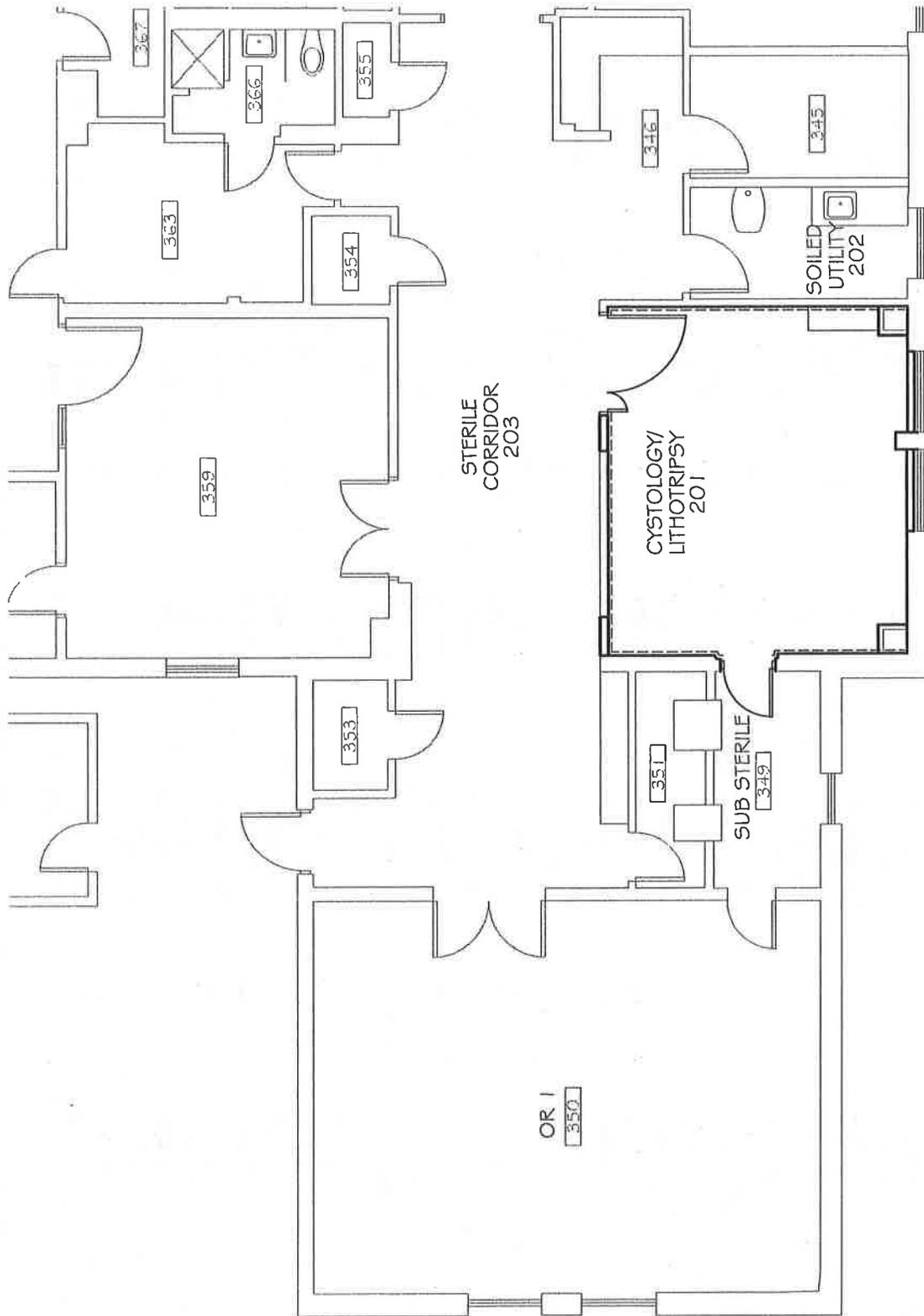
BWSC BUREAU OF WEIGHTS & MEASUREMENTS & CENTER OF GRAVITY



Google Google Maps



Imagery ©2015 Google, Map data ©2015 Google 100 ft



EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY NEED PROJECTIONS
BY COUNTY AND STATE TOTAL, 2014 DATA, PROJECTED TO 2018

STATE UTILIZATION RATE 0.0012927

COUNTY	PROJ POP	NEED
TENNESSEE	6,962,031	9,000
ANDERSON	78,387	101
BEDFORD	51,672	67
BENTON	16,711	22
BLED SOE	13,394	17
BLOUNT	136,505	176
BRADLEY	107,651	139
CAMPBELL	41,654	54
CANNON	14,658	19
CARROLL	28,298	37
CARTER	58,274	75
CHEATHAM	41,269	53
CHESTER	18,633	24
CLAIBORNE	34,263	44
CLAY	7,876	10
COCKE	37,335	48
COFFEE	56,909	74
CROCKETT	14,982	19
CUMBERLAND	63,778	82
DAVIDSON	698,061	902
DECATUR	12,029	16
DEKALB	19,936	26
DICKSON	54,959	71
DYER	39,607	51
FAYETTE	46,608	60
FENTRESS	19,082	25
FRANKLIN	42,395	55
GIBSON	51,934	67
GILES	29,787	39
GRAINGER	24,244	31
GREENE	73,620	95
GRUNDY	13,379	17

COUNTY	PROJ POP	NEED
HAMBLEN	66,195	86
HAMILTON	362,471	469
HANCOCK	6,981	9
HARDEMAN	27,284	35
HARDIN	26,680	34
HAWKINS	59,311	77
HAYWOOD	18,274	24
HENDERSON	29,836	39
HENRY	33,771	44
HICKMAN	26,876	35
HOUSTON	9,014	12
HUMPHREYS	19,090	25
JACKSON	12,251	16
JEFFERSON	57,073	74
JOHNSON	18,952	24
KNOX	477,780	618
LAKE	8,441	11
LAUDERDALE	28,930	37
LAWRENCE	43,518	56
LEWIS	12,912	17
LINCOLN	35,104	45
LOUDON	56,118	73
MCMINN	55,100	71
MCNAIRY	27,486	36
MACON	23,838	31
MADISON	104,799	135
MARION	28,627	37
MARSHALL	33,885	44
MAURY	90,666	117
MEIGS	12,345	16
MONROE	49,048	63
MONTGOMERY	211,602	274

COUNTY	PROJ POP	NEED
MOORE	6,923	9
MORGAN	23,848	31
OBION	31,625	41
OVERTON	23,885	31
PERRY	8,362	11
PICKETT	5,237	7
POLK	17,627	23
PUTNAM	81,972	106
RHEA	34,582	45
ROANE	55,990	72
ROBERTSON	76,231	99
RUTHERFORD	337,990	437
SCOTT	23,058	30
SEQUATCHIE	16,399	21
SEVIER	104,829	136
SHELBY	970,212	1,254
SMITH	20,534	27
STEWART	14,210	18
SULLIVAN	159,393	206
SUMNER	184,532	239
TIPTON	69,239	90
TROUSDALE	8,564	11
UNICOI	19,003	25
UNION	20,124	26
VAN BUREN	5,668	7
WARREN	41,167	53
WASHINGTON	137,400	178
WAYNE	17,551	23
WEAKLEY	36,300	47
WHITE	28,037	36
WILLIAMSON	225,526	292
WILSON	133,865	173

DATA SOURCES: HEALTH SERVICES AND DEVELOPMENT AGENCY EQUIPMENT REGISTRY, as of Aug 10, 2015.

HEALTH STATISTICS POPULATION ESTIMATES 2014.

UNIVERSITY OF TENNESSEE, CENTER FOR BUSINESS AND ECONOMIC RESEARCH 2010-2030 POPULATION PROJECTIONS (2015 VERSION).

PREPARED BY: TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF POLICY, PLANNING AND ASSESSMENT, OFFICE OF HEALTH STATISTICS.

Run: Aug 2015

Lithotripsy - 2013		
County	Hospital Name	Total
Campbell	Fort Sanders Regional Medical Center	*
	Methodist Medical Center of Oak Ridge	19
	North Knoxville Medical Center	24
	Parkwest Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	28
Campbell Total		81
Claiborne	Fort Sanders Regional Medical Center	*
	Franklin Woods Community Hospital	*
	North Knoxville Medical Center	*
	Parkwest Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	14
Claiborne Total		31
Scott	Fort Sanders Regional Medical Center	*
	Methodist Medical Center of Oak Ridge	21
	North Knoxville Medical Center	*
	Physicians Regional Medical Center	*
	The University of Tennessee Med. Cntr.	*
Scott Total		36

Note:

* Data is suppressed when the number of visits is less than 11
 (1)Lithotripsy is identified by Lithotripsy flag and/or CPT code 50590

Data Source: Tennessee Department of Health, Division of Policy, Planning and Assessment. Hospital Disc



Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Re: Tennova Healthcare -- LaFollette Medical Center
CON application for Lithotripsy

Dear Ms. Hill:

I am a board certified Urologist and I have recently joined the medical staff of LaFollette Medical Center, having relocated by practice from Somerset, Kentucky. The proposed establishment of a lithotripsy service at LMC would be of tremendous benefit to patients in need of this health care service.

I have performed lithotripsy treatments for hundreds of patients, and I know the benefit of early and effective treatment. Renal stones are extremely painful to the patient. Requiring patients to forego or unduly delay treatment not only prolongs suffering, it can lead to further healthcare complications.

I urge you to approve this certificate of need, so we can bring this service to a currently unserved area. Thank you for your consideration.

Sincerely,

Sean DeLair, Urologist

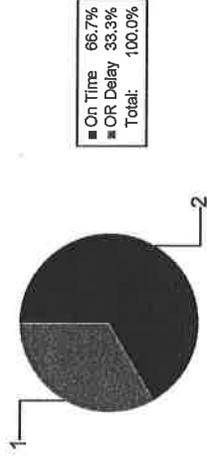
Q4_2014

Quarterly Review

Trending

Patients	Stones	Duration (min)	Age
Q4-2014	3	55.3	62.7
Q3-2014	7	47.6	52.6
Q2-2014	6	49.3	56.8
Q1-2014	3	53.0	57.3

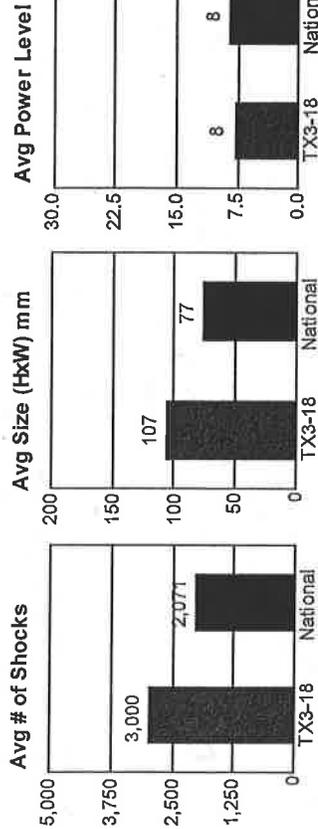
Procedure Status



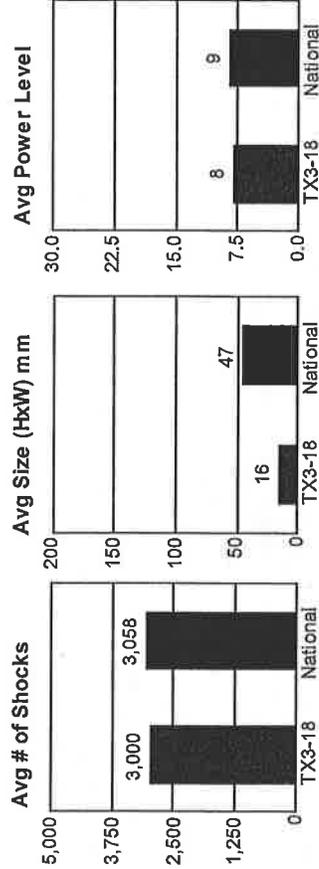
Quality Indicators

Bilateral Procedures:	0/3	0%	10%*
Retreatment Rate:	1/3	33%	10%*
Adjunctive Procedures:	0/3	0%	33%**
Avg Fluoro Time (min):		2:36	5:00*
Stones Under 4mm:	0/3	0%	10%*

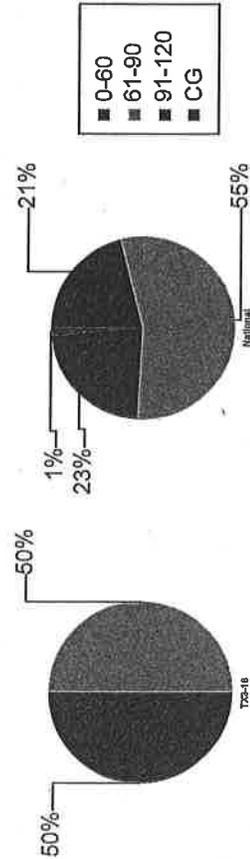
Renal Stones: 2



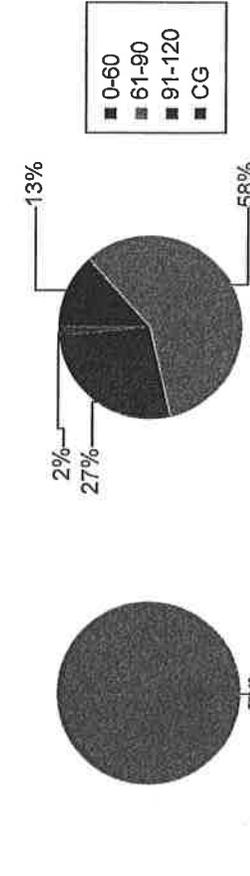
Ureteral Stones: 1



Renal Shocks Per Minute (%)



Ureteral Shocks Per Minute (%)



POPULATION AND DEMOGRAPHICS OF SERVICE AREA				
Variable	Campbell County	Claiborne County	Scott County	State of Tennessee
Current Year (2015), Age 65+	7,793	6,000	3,615	1,012,937
Projected Year (2018), Age 65+*	8,122	6,378	3,857	1,102,413
Age 65+, % Change	4.2%	6.3%	6.7%	8.8%
Age 65+, % Total (CY)	18.7%	18.3%	16.5%	15.2%
Age 65+, % Total (PY)	19.1%	19.2%	17.5%	16.1%
CY, Total Population (2015)	41,783	32,765	21,915	6,649,438
PY, Total Population (2018)	42,566	33,280	21,969	6,833,509
Total Pop. % Change	1.9%	1.6%	0.2%	2.8%
TennCare Enrollees (July, 2015)	13,151	9,274	7,964	1,433,687
TennCare Enrollees as a % of Total Population(CY)	31.5%	28.3%	36.3%	21.6%
Median Age (2010 Census)	42	41	38	38
Median Household Income ('09-'13)	\$31,943	\$33,229	\$28,401	\$44,298
Population % Below Poverty Level ('09-'13)	23.8%	22.9%	28.3%	17.6

Sources: Population, <http://tn.gov/health/article/statistics-con>; TennCare enrollment, TennCare Bureau website; Age, TACIR County Profiles website; Income and poverty level, Census Bureau QuickFacts.



July 31, 2015

Ms. Melanie Hill
Executive Director
Tennessee Health Services and Development Agency
500 Deaderick Street, 9th Floor
Nashville, TN 37243

Re: Funding Support for Certificate of Need Application LaFollette Medical Center-Lithotripsy

Dear Ms. Hill:

CHS / Community Health Systems, Inc., the parent of HMA Campbell County, LLC, d/b/a LaFollette Medical Center, the entity which operates LaFollette Medical Center, has internal funds available for the commitment to the following project, with an approximate project cost of \$793,782. CHS/Community Health Systems, Inc. had cash flow from operating activities of \$1,615 million in its fiscal year ending 12/31/14, and currently maintains a \$1 billion revolving credit facility with excess of \$900 million as of 7/31/15 available to fund future cash needs. CHS / Community Health Systems, Inc. is committed to this project and will advance funds as necessary to complete this project.

Should you need anything further, I can be reached at 615-465-7015.

Regards,

A handwritten signature in black ink, appearing to read "Anita H. Passarella", written over a faint, larger version of the same signature.

Anita H. Passarella
Director Treasury Management, Finance

Cc: Wes Griffith
Chief Financial Officer
LaFollette Medical Center TN

Table of Contents

COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

	Year Ended December 31,		
	2014	2013	2012
	(In millions, except share and per share data)		
Operating revenues (net of contractual allowances and discounts)	\$ 21,561	\$ 14,853	\$ 14,747
Provision for bad debts	2,922	2,034	1,914
<i>Net operating revenues</i>	<u>18,639</u>	<u>12,819</u>	<u>12,833</u>
<i>Operating costs and expenses:</i>			
Salaries and benefits	8,618	6,107	5,992
Supplies	2,862	1,975	1,953
Other operating expenses	4,322	2,818	2,807
Government settlement and related costs	101	102	—
Electronic health records incentive reimbursement	(259)	(162)	(123)
Rent	434	279	264
Depreciation and amortization	1,106	771	714
Amortization of software to be abandoned	75	—	—
<i>Total operating costs and expenses</i>	<u>17,252</u>	<u>11,890</u>	<u>11,607</u>
<i>Income from operations</i>	1,380	929	1,226
Interest expense, net of interest income of \$5, \$3 and \$3 in 2014, 2013 and 2012, respectively	972	613	621
Loss from early extinguishment of debt	73	1	115
Equity in earnings of unconsolidated affiliates	(48)	(43)	(42)
Impairment of long-lived assets	41	12	10
<i>Income from continuing operations before income taxes</i>	<u>342</u>	<u>346</u>	<u>522</u>
Provision for income taxes	82	104	164
<i>Income from continuing operations</i>	<u>260</u>	<u>242</u>	<u>358</u>
<i>Discontinued operations, net of taxes:</i>			
Loss from operations of entities sold or held for sale	(7)	(21)	(12)
Impairment of hospitals sold or held for sale	(50)	(4)	—
<i>Loss from discontinued operations, net of taxes</i>	<u>(57)</u>	<u>(25)</u>	<u>(12)</u>
<i>Net income</i>	203	217	346
Less: Net income attributable to noncontrolling interests	111	76	80
<i>Net income attributable to Community Health Systems, Inc. stockholders</i>	<u>\$ 92</u>	<u>\$ 141</u>	<u>\$ 266</u>
<i>Basic earnings (loss) per share attributable to Community Health Systems, Inc. common stockholders(1):</i>			
Continuing operations	\$ 1.33	\$ 1.80	\$ 3.11
Discontinued operations	(0.51)	(0.27)	(0.13)
<i>Net income</i>	<u>\$ 0.82</u>	<u>\$ 1.52</u>	<u>\$ 2.98</u>
<i>Diluted earnings (loss) per share attributable to Community Health Systems, Inc. common stockholders(1):</i>			
Continuing operations	\$ 1.32	\$ 1.77	\$ 3.09
Discontinued operations	(0.51)	(0.27)	(0.13)
<i>Net income</i>	<u>\$ 0.82</u>	<u>\$ 1.51</u>	<u>\$ 2.96</u>
<i>Weighted-average number of shares outstanding</i>			
Basic	111,579,088	92,633,332	89,242,949
Diluted	<u>112,549,320</u>	<u>93,815,013</u>	<u>89,806,937</u>

(1) Total per share amounts may not add due to rounding.

See notes to the consolidated financial statements.

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COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year Ended December 31,		
	2014	2013 (in millions)	2012
Net income	\$ 203	\$ 217	\$ 346
Other comprehensive income (loss), net of income taxes:			
Net change in fair value of interest rate swaps, net of tax of \$7, \$34 and \$26 for the years ended December 31, 2014, 2013 and 2012, respectively	13	60	46
Net change in fair value of available-for-sale securities, net of tax	—	2	3
Amortization and recognition of unrecognized pension cost components, net of tax (benefit) of \$(9), \$9 and \$(3) for the years ended December 31, 2014, 2013 and 2012, respectively	(9)	16	(10)
Other comprehensive income	4	78	39
Comprehensive income	207	295	385
Less: Comprehensive income attributable to noncontrolling interests	111	76	80
Comprehensive income attributable to Community Health Systems, Inc. stockholders	<u>\$ 96</u>	<u>\$ 219</u>	<u>\$ 305</u>

See notes to the consolidated financial statements.

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COMMUNITY HEALTH SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	2013
	(In millions, except share data)	
ASSETS		
<i>Current assets:</i>		
Cash and cash equivalents	\$ 509	\$ 373
Patient accounts receivable, net of allowance for doubtful accounts of \$3,504 and \$2,438 at December 31, 2014 and 2013, respectively	3,409	2,323
Supplies	557	371
Prepaid income taxes	30	107
Deferred income taxes	341	101
Prepaid expenses and taxes	192	127
Other current assets (including assets of hospitals held for sale of \$38 and \$40 at December 31, 2014 and 2013, respectively)	528	345
Total current assets	5,566	3,747
<i>Property and equipment:</i>		
Land and improvements	946	623
Buildings and improvements	8,791	6,225
Equipment and fixtures	4,527	3,614
Property and equipment, gross	14,264	10,462
Less accumulated depreciation and amortization	(4,095)	(3,411)
Property and equipment, net	10,169	7,051
<i>Goodwill</i>		
Other assets, net of accumulated amortization of \$827 and \$535 at December 31, 2014 and 2013 respectively (including assets of hospitals held for sale of \$90 and \$94 at December 31, 2014 and 2013, respectively)	2,735	1,895
Total assets	\$27,421	\$ 17,117
LIABILITIES AND EQUITY		
<i>Current liabilities:</i>		
Current maturities of long-term debt	\$ 235	\$ 167
Accounts payable	1,293	949
Deferred income taxes	23	3
<i>Accrued liabilities:</i>		
Employee compensation	955	690
Interest	227	112
Other (including liabilities of hospitals held for sale of \$10 and \$24 at December 31, 2014 and 2013, respectively)	856	537
Total current liabilities	3,589	2,458
<i>Long-term debt</i>		
Deferred income taxes	16,681	9,286
Other long-term liabilities	845	906
Other long-term liabilities	1,692	977
Total liabilities	22,807	13,627
<i>Reasonable noncontrolling interests in equity of consolidated subsidiaries</i>		
Commitments and contingencies (Note 16)	531	358
EQUITY		
<i>Community Health Systems, Inc. stockholders' equity:</i>		
Preferred stock, \$.01 par value per share, 100,000,000 shares authorized; none issued	1	1
Common stock, \$.01 par value per share, 300,000,000 shares authorized; 117,701,087 shares issued and 116,725,538 shares outstanding at December 31, 2014, and 95,987,032 shares issued and 95,011,483 shares outstanding at December 31, 2013	2,095	1,256
Additional paid-in capital	(7)	(7)
Treasury stock, at cost, 975,549 shares at December 31, 2014 and 2013	(63)	(67)
Accumulated other comprehensive loss	1,977	1,885
Retained earnings	4,003	3,068
Total Community Health Systems, Inc. stockholders' equity	80	64
<i>Noncontrolling interests in equity of consolidated subsidiaries</i>		
Total equity	4,083	3,132
Total liabilities and equity	\$27,421	\$ 17,117

See notes to the consolidated financial statements.

2015 AUG 12 10:23 AM

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF CAMPBELL

R. Mark Cain, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

[Signature]
SIGNATURE/TITLE CEO

Sworn to and subscribed before me the 12 day of August, 2015, a Notary Public for Campbell County, Tennessee.



[Signature]
NOTARY PUBLIC

My commission expires 9/13/15.

Supplemental #1
-COPY-

TENNOVA LaFollette
(LITHOTRIPSY)

CN1508-032

August 27, 2015**1:38 pm****SUPPLEMENTAL RESPONSES****CERTIFICATE OF NEED APPLICATION****FOR****TENNOVA HEALTHCARE -
LAFOLLETTE MEDICAL CENTER****Initiation of Part-Time Lithotripsy Service****Campbell County, Tennessee****Project No. CN1508-032****August 27, 2015****Contact Person:****Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247**

1. Section B, Project Description, Item 1

Approximately what percentage of lithotripsy procedures will be performed on an emergency basis?

Approximately 10%.

Will Dr. DeLair bill separately for services or will his charges be covered under a global fee?

Dr. DeLair will bill separately for his professional services.

Does Dr. DeLair participate in Medicare and contract with all the TennCare MCOs that the hospital does?

Yes. Dr. DeLair is an employed physician. He participates in Medicare and is in network with all of the TennCare MCOs with which the hospital is in network.

What are the applicant's expectations of physician referrals by specialty to the proposed ESWL mobile service? Please complete the table below.

Specialty	Physicians practicing in PSA/SSA	ESWL Referrals Year 1
Family Practice	26	
Internal Medicine	10	
OB/GYN	2	
Orthopedics	0	
General Surg	8	
Urology	1	165
Other	Podiatry 2 Cardiology 2 Oncology 1	
TOTAL	52	

The number of physicians by specialty is the hospital's estimate based on various sources in the community. There is no such data routinely maintained by TH-LMC.

All referrals from lithotripsy treatment must come from an Urologist. Some portion of the patients will be referred from a different specialty to the Urologist. The vast portion of these referrals will be from Family Practice and Internists, but the applicant was not able to accurately quantify the number of those referrals.

2. Section B, Project Description, Item II. A.

Where will the lithotripsy unit be stored when not in use?

It will be in the possession of the mobile vendor, Kentucky I Lithotripsy, LLC.

Will the lithotripsy unit be at the hospital full-time or will the vendor be using it at other locations during the week?

The vendor will be using it at other locations when it is not in use at LaFollette Medical Center.

3. Section B, Project Description, Item B. II.C.

One key benefit appears to be the use of the service as an alternative to invasive surgeries. Can the applicant offer some insight as to the magnitude of same in the PSA and the potential reduction in surgeries resulting from this project?

Shock wave lithotripsy is an alternative to an invasive surgical procedure which must be performed through the patient's back. Lithotripsy is a very low risk, non-invasive, less painful procedure than the surgical alternative and also results in less lost work time for the patient (if employed). Lithotripsy has a 80-90% success rate, and the benefits to the patient compared to the surgical alternative are numerous and obvious.

There is no publicly available data as to the number of kidney stone surgeries performed in the service area, so any potential impact on the incidence of such surgical procedures cannot be accurately quantified.

4. Section B, Project Description, Item E.2

Please also describe the date of manufacture of the unit, its current years in service and expected useful life, and any technological advantages in comparison to other ESWL models.

The date of manufacture is July 2005.

Its current years in service are 10 years.

Its expected useful life is 20 plus years.

Technological advantages in comparison to other ESWL models:

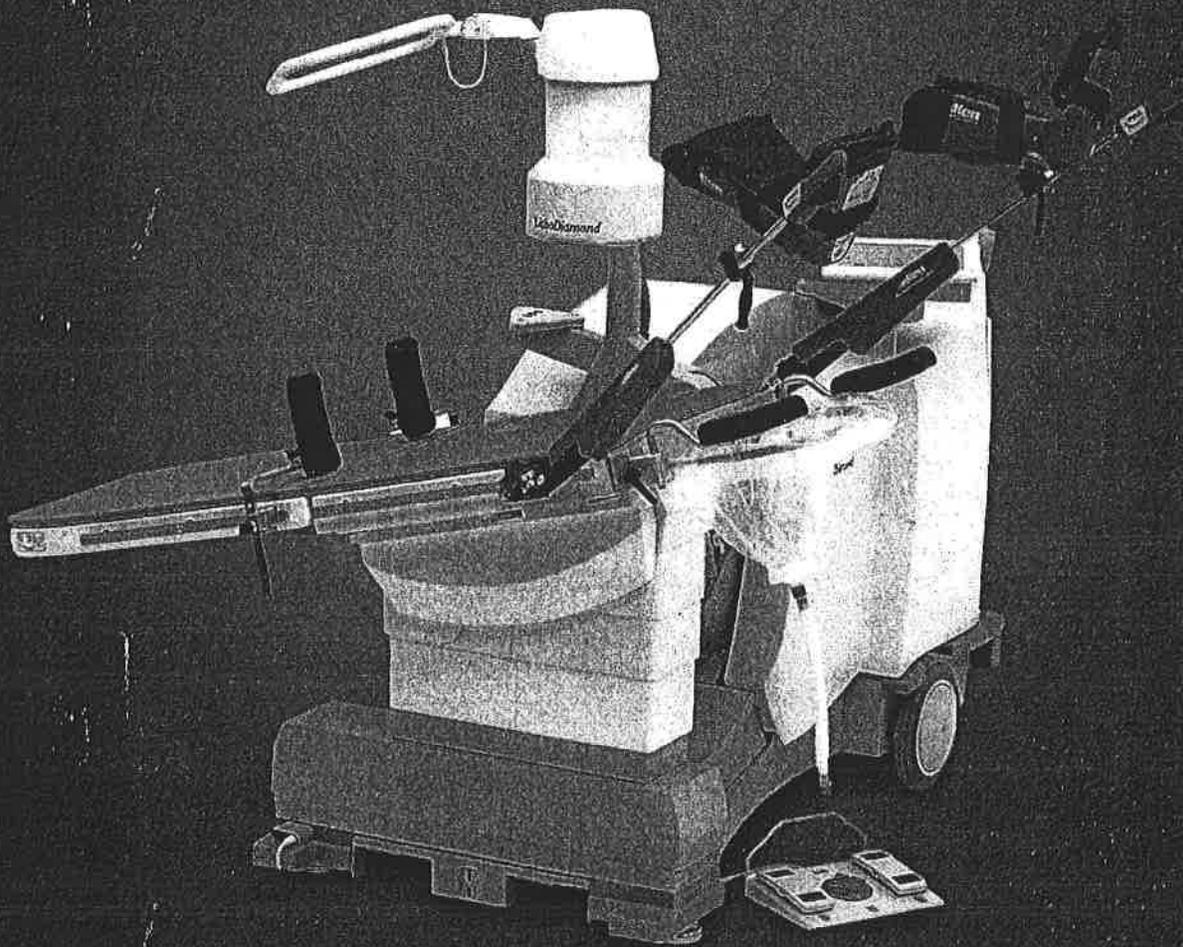
- Large focus area for enhanced fragmentation and reduced negative effects of respiratory excursion.

- Allows for additional urological procedures without need to reposition (radio transparent table top).
- +/- trendelenburg positioning.
- Enhanced imaging.

An informational brochure is attached following this response.

LITHODIAMOND®

Multifunctional Lithotripsy System



www.healthtronics.com

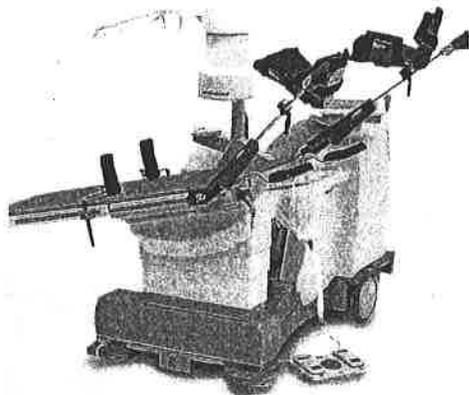


HealthTronics
We share your passion

1:38 pm

A Focused Approach

For two decades, HealthTronics has set the standard with innovative diagnostic and treatment devices like the LithoDiamond® Multifunctional Lithotripsy System. Developed specifically to disintegrate renal and ureteral stones, the LithoDiamond features state-of-the-art technology in a compact design to deliver an exceptionally efficient and affordable lithotripsy system. The LithoDiamond provides the highest level of clinical results for both Urologist and patient.

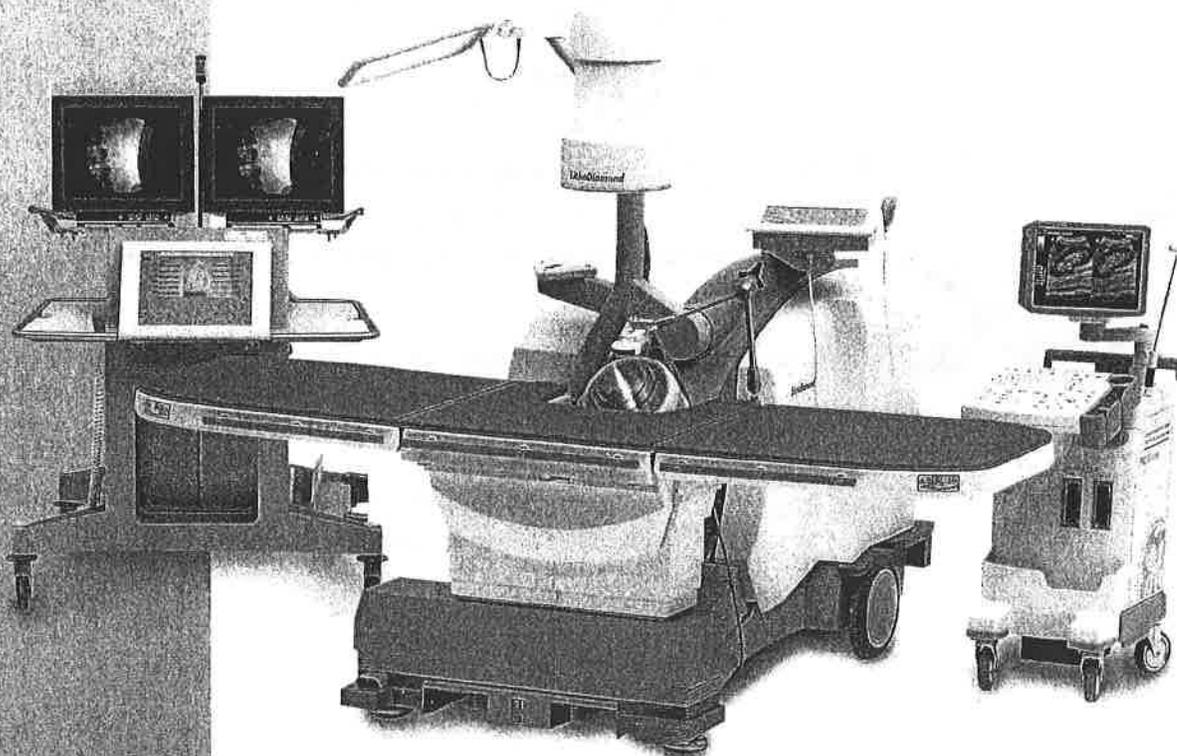


Large Focal Zone

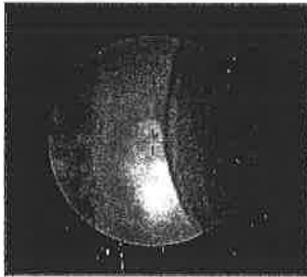
Using proven electrohydraulic shockwave generation, the LithoDiamond delivers safe and effective stone fragmentation. Featuring the largest focal zone (11 x 96 mm) available on the market today, the LithoDiamond provides enhanced fragmentation and dramatically reduces the negative effects of respiratory excursion during the treatment.

Integrated Therapy Modules

The shockwave generator and x-ray system have been combined with the patient table to form a powerful, yet compact, lithotripsy system. The mobile control console can be positioned in or out of the treatment area and features two high-resolution monitors and a menu system that allows for easier shockwave, x-ray, and table control. An optional remote monitoring system offers even faster service and reduced downtime.

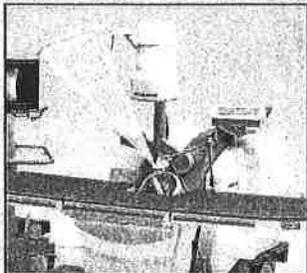
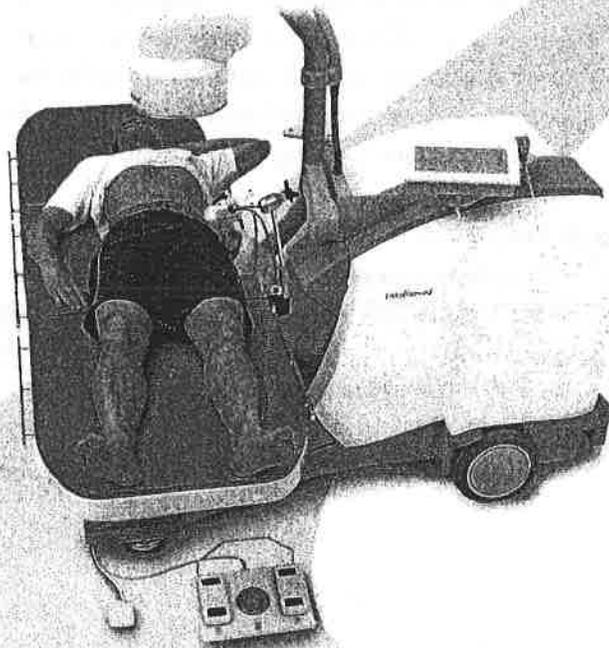


1:38 pm



Superb High Resolution Imaging

The LithoDiamond® employs a contrast optimized fluoroscopic imaging system specifically designed for lithotripsy that delivers excellent image resolution with minimum radiation exposure. This makes locating stones and patient positioning much simpler.



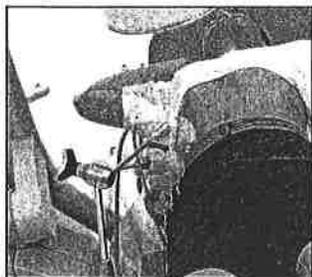
A Versatile Urological Workstation

The LithoDiamond allows the operator to perform additional urologic procedures on the table without the need to reposition the patient for treatment.

The table provides both positive and negative Trendelenburg tilt, and a foot pedal that allows the operator to reposition the table easily during endoscopic procedures.

The unit is also equipped with stirrups and a flexible holder for disposable drain bags. The optional printer can provide a hard copy of all images during treatment.

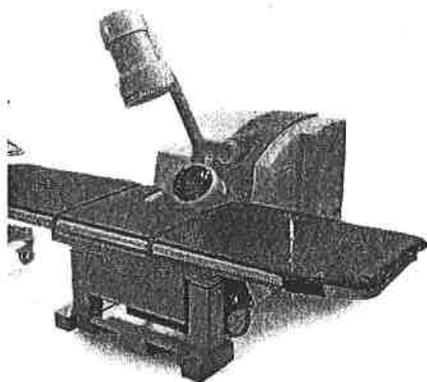
1:38 pm



Advanced Positioning

The LithoDiamond can also use ultrasonic localization to pinpoint the calculi. The standard transducer for abdominal examinations will localize and position the stone while the computerized system automatically moves the patient into the appropriate treatment position.

Ultrasound and x-ray may be used simultaneously.



Shorter Treatment Times

Because it has been designed specifically for lithotripsy, with a highly advanced locating system, the LithoDiamond has the added advantage of greatly reduced treatment times. With the LithoDiamond, treatment generally takes only 20 or 30 minutes.

LithoDiamond Features and Benefits

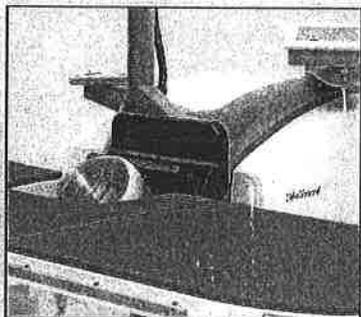
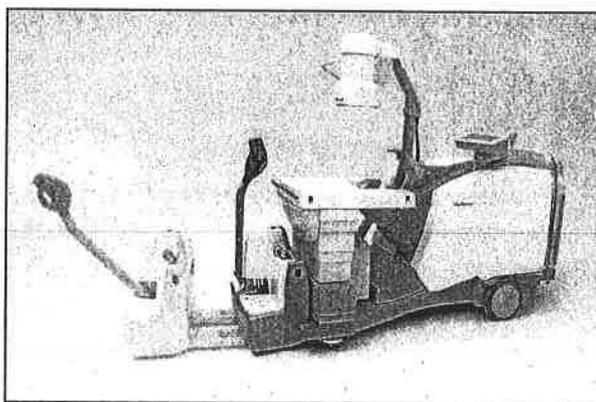
- *Comfortable.* Treatments can be performed without anesthesia.
- *Simple.* A menu-guided user interface makes it easy to control all the unit's functions.
- *Quick and Safe.* Advanced x-ray locating system for simple and accurate stone positioning.
- *Economy.* High availability, short treatment time, and easy servicing for distinct savings over other lithotripsy systems.
- *Patient Convenience.* Low table height for easier patient loading.
- *Flexibility.* Can be used as either a stationary or a transportable system.
- *Multifunctional.* Can be used to perform routine endourology procedures.

1:38 pm

The Truly Transportable Lithotripter

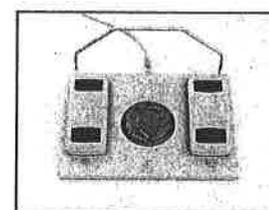
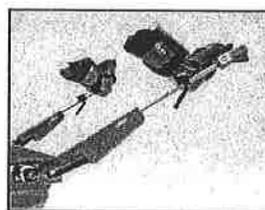
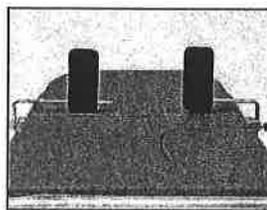
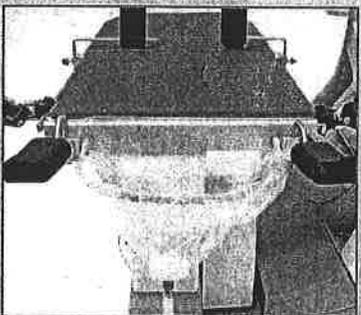
The LithoDiamond® is a "Plug and Go" device. Its quick setup and outstanding mobility, a result of the unit's small dimensions and the easily integrated transport unit, make the LithoDiamond a factor you can rely on in your therapy planning.

When the treatment day is done, the system becomes a compact configuration, which is easily moved onto a transport vehicle via an electric trolley, or placed into a storage area to free up the treatment area.



Accessories

- Arm Support
- Holder for Disposable Drain Bags
- Shoulder Supports
- Stirrups
- Foot Pedals



Item c – Lease/Contract Cost: given the vendor quote for equipment payments on a \$2,400 per procedure basis for an initial term of 1 year, what are the arrangements if for some reason no patients need to be treated on a scheduled day of mobile service? Please clarify what costs the hospital will incur if a patient does not give notice and is a no-show, and the unit comes to the hospital to deliver a service.

If no patients are scheduled for a day the unit is scheduled to be on site at TH-LMC, the mobile vendor will be notified and will not bring the unit. If a patient is scheduled and is a no-show, TH-LMC will not be charged for the procedure. The patient would not incur any liability.

5. Section C, Need, Item 1.a. (Project Specific Criteria-Extra-Corporeal Shock Wave Lithotripsy). Please provide a response for each of the items noted below:

3. Current Service Area Utilization. The patient destination chart from the Department of Health is noted. Please contact Alecia Craighead, Statistical Analyst III at the HSDA office with more current and complete data. Please also complete the following chart:

	2012	2013	2014	% Change '12-'14
Total # resident ESWL procedures	163	156	132	-19%
# residents using Knox Co. Providers	112	115	101	-9.8%
% Residents using Knox Co. providers	68.7%	73.7%	76.5%	7.8%
Total ESWL procedures of Knox Co. providers	1,456	1,573	1,439	-1.1%
% Knox Co. provider reliance on PSA/SSA residents	11.2%	9.9%	9.2%	-2%
# residents using Anderson Co. Providers	51	40	31	-39.22%
% Residents	31.3%	25.6%	23.5%	-7.8%

using Anderson Co. providers				
Total ESWL procedures of Anderson Co. providers	212	192	168	-20.7%
% Anderson Co. provider reliance on PSA/SSA residents	24.1%	20.1%	18.4%	-5.7%

Source: HSDA Medical Equipment Registry 8/24/2015

5. Adequate Staffing and Services – Your response to this item is noted.

Please:

- **Provide some details regarding radiology services. Please identify the names of all radiologists on the hospital's medical staff that apply (with copy of CV, if possible).**

The mobile vendor will supply the Radiologic Technologist, who will be properly trained and certified in the operation of the lithotripsy unit. The radiologic technologist has not been specifically identified by the mobile vendor at this time. None of TH-LMC's radiology medical staff will be involved in the provision of lithotripsy services.

- **Please provide documentation of Dr. DeLair's board certification.**

A letter of verification from The American Board of Urology is attached following this response.

August 27, 2015

1:38 pm

THE AMERICAN BOARD OF UROLOGY

600 Peter Jefferson Parkway
Suite 150
Charlottesville, VA 22911

Phone: 434/979-0059Fax: 434/979-0266www.abu.org**TRUSTEES:**

April 10, 2015

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ADMINISTRATIVE STAFF:*Executive Secretary*

GERALD H. JORDAN, MD

Sean Martin DeLair MD
185 Tatum Point
Somerset KY 42503

Dear Dr. DeLair:

The American Board of Urology verifies that you are a Diplomate.

Your certificate was dated February 28, 2009. Your certificate number is 16501.

Certificates issued by the American Board of Urology on or after January 1, 1985 expire on the anniversary of the date of issue and are valid for ten years only. Your certificate will expire February 28, 2019. A physician who fails to maintain certification by the expiration date is no longer a Diplomate of the Board.

Maintenance of this certificate requires full participation in the American Board of Urology's Maintenance of Certification (MOC) program. You are in compliance with MOC, having successfully completed Levels 1 and 2 in 2011 and 2013, respectively, and you are meeting the requirements of your American Board of Urology certificate.

Sincerely,


Gerald H. Jordan, M.D.
Executive Secretary

GHJ/lrd

- **Will Dr. DeLair have physician back-up when on vacation or unavailable for other reasons?**

Not at this time; Dr. DeLair is the only Urologist on the medical staff. TH-LMC is continuing to explore opportunities that may result in another Urologist joining the medical staff in the future, but no specific plans are in place.

Because the lithotripsy service will be scheduled for specific days, in most instances it will be possible for Dr. DeLair to schedule any absences around the service. In the rare event that an emergent case presents at the E.D. when Dr. DeLair is not available, the patient would be referred or transferred to a lithotripsy provider of the patient's choice following stabilization.

- **It is understood that Dr. DeLair is board-certified in Urology. Are there other training and credentialing requirements of the American College of Surgeon's Advisory Council for Urology besides board certification? If yes, what are they and document that Dr. DeLair meets those requirements.**

No additional training or certification is required beyond board certification. Dr. DeLair has performed or supervised lithotripsy procedures for many years prior to joining the medical staff.

- **What will be the ongoing education plan for Dr. DeLair and other staff associated with the lithotripsy service.**

No on-going education specific to the lithotripsy service is necessary or planned for the staff. All routine annual competencies will be completed for all staff.

10. b. Access- Your response to this item is noted. Please update your response using the more recent data collected from the HSDA equipment registry and use the chart below.

ESWL Use Rates by County per 1,000 Population in Applicant's Service Area

County	2012	2013	2014
Campbell	.19344	.21378	.15190
Claiborne	.12688	.10475	.09814
Scott	.19509	.15464	.16861
Statewide*	.11283	.11689	.12090

Source: HSDA Equipment Registry 8/25/15

*Statewide use rate does not include non-Tennessee residents. This is thought to be the more comparable set of data, since the county use rates obviously do not include non-county residents.

6. Section C, Need, Item 4.A.

Your population table is noted. Please add a column that totals the 3-county service area.

A revised table is attached following this response.

POPULATION AND DEMOGRAPHICS OF SERVICE AREA						
Variable	Campbell County	Claiborne County	Scott County	Service Area Total	State of Tennessee	
Current Year (2015), Age 65+	7,793	6,000	3,615	17,408	1,012,937	
Projected Year (2018), Age 65+*	8,122	6,378	3,857	18,357	1,102,413	
Age 65+, % Change	4.2%	6.3%	6.7%	5.5%	8.8%	
Age 65+, % Total (CY)	18.7%	18.3%	16.5%	18.0%	15.2%	
Age 65+, % Total (PY)	19.1%	19.2%	17.5%	18.8%	16.1%	
CY, Total Population (2015)	41,783	32,765	21,915	96,463	6,649,438	
PY, Total Population (2018)	42,566	33,280	21,969	97,815	6,833,509	
Total Pop. % Change	1.9%	1.6%	0.2%	1.4%	2.8%	
TennCare Enrollees (July, 2015)	13,151	9,274	7,964	30,389	1,433,687	
TennCare Enrollees as a % of Total Population(CY)	31.5%	28.3%	36.3%	31.5%	21.6%	
Median Age (2010 Census)	42	41	38	40 (avg.)	38	
Median Household Income ('09-'13)	\$31,943	\$33,229	\$28,401	\$31,191 (avg.)	\$44,298	
Population % Below Poverty Level ('09-'13)	23.8%	22.9%	28.3%	25% (avg.)	17.6	

Sources: Population, <http://tn.gov/health/article/statistics-con>; TennCare enrollment, TennCare Bureau website; Age, TACIR County Profiles website; Income and poverty level, Census Bureau QuickFacts.

7. Section C, Need, Item 4.B.

Please provide a response to this item.

The question and omitted response are reflected below:

4. A. Describe the demographics of the population to be served by this proposal.

A table reflecting the population and demographics of the service area is attached following the previous response.

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

According to data obtained from the Department of Health, every county in the service area had a higher use rate for lithotripsy services than the state-wide use rate for 2013 (see page 20 of the application).

According to data from the HSDA Equipment Registry, every county in the service area except for Claiborne County in 2013 and 2014, had a higher use rate for lithotripsy services than the state-wide use rate for the years 2012-2014 (see table in response to Supplemental Question 5).

Every county in the service area is designated as a Medically Underserved Area by the United States Health Resources and Services Administration (see page 20 of the application).

There is no existing lithotripsy service in the service area.

The service area has a disproportionately high share of TennCare enrollees (31.5% service area compared to 21.6% state-wide).

A locally accessible lithotripsy service will address these special needs. TH-LMC participates in Medicare and contracts with all TennCare MCOs operating in the area.

8. Section C, Need, Item 5

Your response to this item is noted; however since the application has already noted that significant numbers of patients are traveling to Knox and Anderson County lithotripsy providers, please complete the following table utilizing data from the HSDA Equipment Registry.

Knox/Anderson Co. ESWL Provider	Distance from TH-LMC*	2012 procedures	2013 procedures	2014 procedures
Methodist Medical Center (Anderson)	34 Miles/ 46 min	212	192	168
Fort Sanders Regional Medical Center (Knox)	39 Miles/ 44 min.	143	163	165
North Knoxville Medical Center (Knox)	30 Miles/ 35 min.	289	349	294
Parkwest Medical Center (Knox)	46 Miles/ 51 min	430	437	484
Physicians Regional Medical Center (Knox)	37 Miles/ 43 min	83	71	54
Turkey Creek Medical Center (Knox)	49 Miles/ 53 min	N/A	65	45
University of Tennessee Medical Center (Knox)	40 Miles/ 46 min.	511	488	397

**note: please show in miles & estimated driving time*

Sources: Procedures, HSDA Medical Equipment Registry, 8/25/15; Distances and times, Google Maps

9. Section C, Need, Item 6

The applicant notes that 148 service area residents sought lithotripsy services. The applicant is projecting 165 patients in Year 1, which would suggest a market share of 100%+. Is this a realistic assumption?

The projected number of patients is believed to be reasonable in light of the following considerations:

The projected 165 patients include not only those from the 3 county primary service area, but some from other counties which do not have a local lithotripsy service. Although the number of patients residing in the secondary service area was not quantified, it is reasonable to assume there will be some in-migration from those areas.

The lack of a locally accessible lithotripsy service may be keeping the numbers of treatments provided to service area residents artificially low, as patients may forego treatment or receive alternative forms of treatment.

Because of the per-click lease arrangement, even if the first year projections are not reached the project will still be economically feasible. And, it will still be providing a much needed new health care service in the service area.

Whole Hospital-Other Expenses – Year 1 and 2 of the Other Expense chart on page 30 have the same entries but different totals. Please make the necessary corrections and submit a revised chart.

A revised Other Expenses chart is attached following this response. The reason the entries are identical for both years is these are fixed, not variable expenses.

Lithotripsy Only-Other Expenses - Please provide a detailed Other Expenses Chart.

An itemization of "Other Expenses" for the Projected Data Chart for the Lithotripsy service is attached following this response.

August 27, 2015**1:38 pm**

Projected Data Chart (Lithotripsy Only)

Other Expenses:

Year 1Year 2

Mobile Lithotripsy Lease Payments:

\$396,000

\$407,880

11. Section C, Economic Feasibility, Items 6A and 6 B

Item 6B What is the Medicare allowable fee schedule for the codes listed in your response to 6A?

\$3,112

12. Section C, Economic Feasibility, Items 7 and 8

What is the minimum number of procedures needed for the lithotripsy service to breakeven?

Because (1) this is a per click lease arrangement, (2) no capital expenditure is required, and (3) net revenue per treatment exceeds the cost per treatment, it will be profitable even if only one treatment is provided.

13. Section C, Orderly Development, Item 3

What are the estimated FTE requirements for RN, Surgical Tech, and CRNA?

The estimated FTE for each position is .32.

The Wage for the CRNA is approximately 3.5 times the median wage. Please explain.

The \$250.00 an hour estimated wage is incorrect. The actual estimated hourly rate is \$150.00 an hour. The reason this hourly rate is substantially higher than the median TDLWD rate is the CRNAs providing services for the lithotripsy service will be part-time contracted positions, whereas the TDLWD median wage is presumably based on a full-time position.

In the Projected Data Chart for the lithotripsy service the applicant has allocated \$3,486 in Year 1. Is that enough?

This entry on the Projected Data Chart for the Lithotripsy service is incorrect. A revised Projected Data Chart for the Lithotripsy service is attached following this response.

14. Publishers Affidavit

Your response to this item is noted. We will await the Publishers Affidavit.

The Publisher's Affidavit is attached following this response.

15. Annual Progress Reports-Tennova

CN1106-019 – Mercy Health System, Inc. fka Mercy Medical Center North and currently known as North Knoxville Medical Center-Acquisition of a second linear accelerator. According to the last project update (7/30/2015) a request will be asking for a one year extension to the expiration date, which is December 1, 2015. When does the applicant expect to make that request?

The extension request will be made no later than October 30, 2015.

To: TENNOVA HEALTHCARE

August 27, 2015

1:38 pm

(Advertising) NOTIFICATION OF INTENT TO APPLY FOR (Ref No: 639006)

P.O.#:

PUBLISHER'S AFFIDAVIT

State of Tennessee }

S.S

County of Knox }

Before me, the undersigned, a Notary Public in and for said Hurst first duly sworn, according to law, says that he/she is a Knoxville News-Sentinel, a daily newspaper published at Knoxville the advertisement of:

(The Above-Reference)

of which the annexed is a copy, was published in said paper on 08/09/15 Sun

and that the statement of account herewith is correct to the best of his/her knowledge, information, and belief.

Landy Hurst

Subscribed and sworn to before me this 10th day of August 2015

Ashley Breeden
Notary Public

My commission expires _____ 20_____

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Tennova Healthcare -- LaFollette Medical Center, owned and managed by Campbell County HMA, LLC, a Tennessee limited liability company, intends to file an application for a Certificate of Need for the initiation of extracorporeal shock-wave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus located at 923 East Central Avenue, LaFollette, Campbell County Tennessee. Tennova Healthcare -- LaFollette Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Health Care Facilities. This project involves no change in the number or types of licensed inpatient beds. The estimated project cost is not to exceed \$850,000.

The anticipated date of filing the application is August 14, 2015.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Burr & Forman, LLP, 511 Union Street, Suite 2300, Nashville, Tennessee 37219, 615-724-3247.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to T.C.A. § 68-11-1607(c)(1): (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.



MY COMMISSION EXPIRES: MAY 5, 2019

August 27, 2015

1:38 pm

AUG 27 2015 1:38 PM

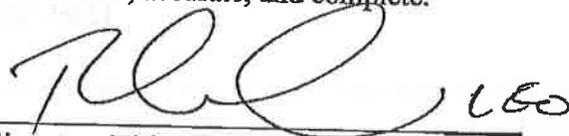
AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF CAMPBELL

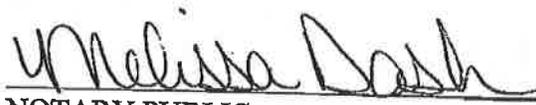
NAME OF FACILITY: TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER

I, Mark Cain, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.



Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 27 day of August 2015, witness my hand at office in the County of Campbell, State of Tennessee.



NOTARY PUBLIC

My commission expires 9/13/15



Supplemental #2
-COPY-

TENNOVA LaFollette
(LITHOTRIPSY)

CN1508-032

August 31, 2015**8:49 am****SECOND SUPPLEMENTAL RESPONSES****CERTIFICATE OF NEED APPLICATION****FOR****TENNOVA HEALTHCARE -
LAFOLLETTE MEDICAL CENTER****Initiation of Part-Time Lithotripsy Service****Campbell County, Tennessee****Project No. CN1508-032****August 31, 2015****Contact Person:****Jerry W. Taylor, Esq.
Burr & Forman, LLP
511 Union Street, Suite 2300
Nashville, Tennessee 37219
615-724-3247**

1. Section C, Economic Feasibility, Item 4 (Projected Data Charts)

Whole Hospital-Other Expenses – The charts submitted do not include the column that identifies the expense item. Please submit a revised page that includes this information.

A revised Other Expenses chart is attached.

Lithotripsy Only-Other Expenses – When taking the mobile lithotripsy lease expense for Year 2 and dividing it by 180 procedures, the result is \$2,266. Since the “per click” arrangement is for \$2,400, please explain this variance. Please also note that if an adjustment is required for this chart, an adjustment will also likely be needed in the Projected Data Chart as well. For example the net revenue per procedure for Year 2 is \$2,938.24 instead of the \$3,112.54 listed in other parts of the application.

A revised Projected Data Chart and Other Expenses page are attached. The incorrect "other expenses" entry for Year 2 does not affect the net revenue per case, because the is not a component of the netted out entries from gross revenue. However, it was discovered that certain other entries for Year 2 were also incorrect.

The attached revised Projected Data Chart reflects a net operating income of \$3,112 for both Year 1 and Year 2.

August 31, 2015

8:49 am

2015 AUG 31 8:49 AM

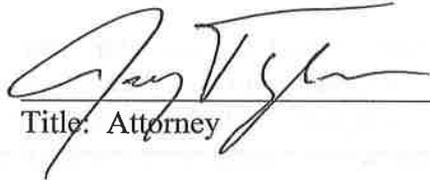
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STATE OF TENNESSEE

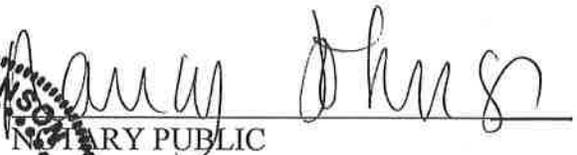
COUNTY OF DAVIDSON

NAME OF FACILITY: TENNOVA HEALTHCARE-LAFOLLETTE MEDICAL CENTER

I, Jerry W. Taylor, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Title: Attorney

Sworn to and subscribed before me, a Notary Public, this the 31st day of August 2015, witness my hand at office in the County of Davidson, State of Tennessee.


NANCY JOHNSON
STATE OF TENNESSEE
NOTARY PUBLIC
DAVIDSON COUNTY, TENN.
My Commission Expires MAR 7, 2017

My commission expires _____



20150807101540082

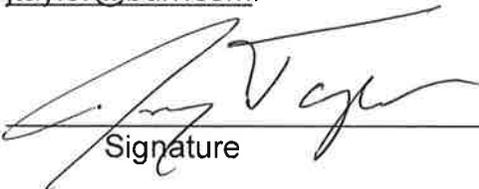
LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Knoxville News Sentinel, which is a newspaper of general circulation in Campbell County, Tennessee, on or before August 9, 2015 for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that Tennova Healthcare -- LaFollette Medical Center, owned and managed by Campbell County HMA, LLC, a Tennessee limited liability company, intends to file an application for a Certificate of Need for the initiation of extracorporeal shockwave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus located at 923 East Central Avenue, LaFollette, Campbell County Tennessee. Tennova Healthcare -- LaFollette Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Health Care Facilities. This project involves no change in the number or types of licensed inpatient beds. The estimated project cost is not to exceed \$850,000.

The anticipated date of filing the application is August 14, 2015.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Burr & Forman, LLP, 511 Union Street, Suite 2300, Nashville, Tennessee 37219, 615-724-3247, jtaylor@burr.com.


Signature

8-7-15
Date

=====
The published Letter of Intent contains the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.
=====

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: October 31, 2015

APPLICANT: Tennova LaFollette Medical Center
923 East Central Avenue
LaFollette, Tennessee 37766

CN1508-032

CONTACT PERSON: Jerry Taylor, Esquire
501 Union Street, Suite 2300
Nashville, Tennessee 37219

COST: \$440,203

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Tennova Healthcare LaFollette Medical Center, (TH-LMC) located at 923 East Central Avenue, LaFollette (Campbell County); Tennessee seeks Certificate of Need (CON) approval for the initiation of extracorporeal shockwave lithotripsy services through use of a leased mobile lithotripsy unit on a part-time basis on the hospital campus. The applicant seeks authorization for up to three days per week. The services will be provided in existing space and no construction will be involved.

The hospital is owned by Campbell County HMA, LLC. It is affiliated through several subsidiaries with Community Health Systems, Inc. An organizational chart is provided in Attachment B, I.

The total project cost is \$440,203 and will be funded through operating revenues or, if necessary, through cash reserves of Community Health Systems, Inc.

This application has been placed on the Consent Calendar. Tenn. Code Ann. § 68-11-1608 Section (d) states the executive director of Health Services and Development Agency may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's service area includes Campbell, Claiborne, and Scott counties.

County	2015 Population	2019 Population	% Increase or (Decrease)
Campbell	41,357	97,69	0.9%
Claiborne	33,546	34,496	2.8%
Scott	22,776	23,145	1.6%
Total	97,679	99,362	2.2%

Source: *Tennessee Population Projections 2000-2020, 2013 Revision*, and *2013 Joint Annual Report of Home Health Agencies*, Tennessee Department of Health, Division of Health Statistics

The applicant’s service area accounts for 89% of admissions at TH-LMC.

Currently there is no lithotripsy units located in the three county service area. The closest units are located in Knox and Anderson counties, 45 minutes to an hour drive time away. TH-LMC has not had a urologist on the medical staff until Dr. Sean DeLair relocated his practice from Kentucky to LaFollette in August 2015. Dr. DeLair has significant experience in delivering lithotripsy treatments and know from experience the need for lithotripsy services in rural counties.

The applicant reports from 2013-2015, 358 patients with a discharge diagnosis of “possible urology” presented and were discharged through TH-LMC’s emergency department per year. TH-LMC states not all of these cases were kidney stones or candidates for lithotripsy but some portion of these undoubtedly were. Prior to Dr. DeLair relocating his practice to LaFollette, these patients could not be treated at TH-LMC and had to seek treatment in Knox or Anderson counties.

The Tennessee Department of Health calculated the need for lithotripsy in the chart

Extra-Corporeal Shockwave Lithotripsy Need in 2018

County	2018
Campbell	54
Claiborne	44
Scott	30
Total	128

Tennessee Department of Health, Division of Policy, Planning, and Assessment

The Tennessee Department of Health analyzed hospital discharge data to identify the total number lithotripsy patients in 2013 from Campbell, Claiborne, and Scott counties.

Extra-Corporeal Shockwave Lithotripsy Visits in 2013

County	2018
Campbell	81
Claiborne	14
Scott	36
Total	131

Tennessee Department of Health, Division of Policy, Planning, and Assessment

TH-LMC projects 165patients in year one and 180 patients in year two.

TENNCARE/MEDICARE ACCESS:

TH-LMC participates in both the Medicare and Medicaid programs. The applicant contracts with BlueCare, United Healthcare Community Plan, and TennCare Select.

The applicant projects Medicare revenues of \$305,521 or 59.5% of gross revenues and TennCare revenues of \$90,372 or 17.6% of gross revenues in year one.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and if the projections are based on the applicant’s anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located on page 24 of the application. The total project cost is \$440,203.

Historical Data Chart: The Historical Data Chart is located on 27 Of the application. The applicant reports 2,359, 2,586, and 2,416 admissions in 2012, 2013, and 2014, respectively; with net operating revenues of \$5,608,800, \$7,422,408, and \$7,513,932 each year.

Projected Data Chart: The Projected Data Chart is located in Supplemental 2, page R31. The applicant projects 165 and 180 in years one and two with net operating revenues of \$94,277.70 and \$102,848.40 each year, respectively.

The applicant's gross charge for lithotripsy is \$9,337.61, with an average deduction of \$6,225.61, resulting in a net charge of \$3,112.00

TH-LMC identified no other cost effective alternative. The leased part-time service agreement calls for a fixed payment per procedure by the hospital to the vendor. The proposal requires little or no out of pocket capital expenditures and can financially sustain itself through operating revenues.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The applicant has contracts with Team Health for Emergency Department coverage, Resource Anesthesia for CRNA coverage, Innovative Pathologists, Abercrombie for Radiology, Healogics for Wound Care, and a transfer agreement with University of Tennessee Medical Center.

The project will have a positive effect on the healthcare system. There are currently no lithotripsy providers in the three county service area.

The applicant will utilize current hospital; staff which includes .32 FTE RN, .32 Surgical Tech, and .32 FTE CRNA.

TH-LMC has training affiliations with numerous educational institutions. These are listed on page 36 of the application.

TH-LMC is licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by Joint Commission.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

**CERTIFICATE OF NEED STANDARDS AND CRITERIA
EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY SERVICES**

Standards and Criteria

- 1. Determination of Need:** The need for ESWL services is determined by applying the following formula:

$$N = (U \times P) + O$$

N = number of ESWL services procedures needed in a Service Area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state as determined by the Tennessee Department of Health);

P = projection of population (in thousands) in the service area as determined by the Tennessee Department of Health for Tennessee counties and the United States Census Bureau for non-Tennessee counties; and

O = the number of out-of-state resident procedures performed within the applicant's Service Area in the same time frame used to determine U based upon publically reported data. The applicant should document the methodology used to count volume in out-of-state resident procedures and, if different from the definition of "procedure" described in these standards and criteria, should distinguish out-of-state procedures from in-state cases.

The need shall be based upon the Service Area's current year's population projected three years forward.

The Tennessee Department of Health calculated the need for lithotripsy below.

Extra-Corporeal Shockwave Lithotripsy Need in 2018

County	2018
<i>Campbell</i>	<i>54</i>
<i>Claiborne</i>	<i>44</i>
<i>Scott</i>	<i>30</i>
Total	128

Tennessee Department of Health, Division of Policy, Planning, and Assessment

- 2. Minimum Volume Standard:** Applicants proposing to acquire and operate an ESWL services unit must project a minimum utilization of at least 250 procedures per year by the third year of operation, based on full-time use of an ESWL unit. The applicant must also document and provide data supporting the methodology used to project the patient utilization. An application to provide ESWL services on a part-time basis shall convert its projected use to that of a full-time equivalent ESWL unit.

The applicant seeks authorization three days per week. The pro-rated minimum is 150. The applicant projects 165 in year one.

- 3. Current Service Area Utilization:** The applicant should document that all existing providers of ESWL services within the proposed Service Area each performed at least 300 ESWL procedures per year during the most recent 12 month period for which data are available. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. To characterize existing providers located within Tennessee, the applicant should use data provided by the Health Services and Development Agency. To characterize providers located outside of Tennessee, the applicant should use publicly available data, if available, and describe in its application the methodology these providers use to count volume.

There are no lithotripsy providers in the three county service area.

In addition, the applicant should provide the HSDA with a report of patient destination for ESWL services based on the most recent 12 months of publicly reported data. This report should list all facilities that provided ESWL services to residents of the proposed Service Area and the number of ESWL procedures performed on residents of the Service Area for each facility. The Tennessee Department of Health will assist applicants in generating this report utilizing the HDDS.

The applicant provides this information in Supplemental 1.

- 4. Adverse Impact on Existing Providers:** An application for ESWL services should not be approved if the new program will cause the annual caseload of existing ESWL programs within the Service Area to drop below an average of 300 procedures. The utilization by ESWL units that operate on a part-time basis shall be converted to that of a full-time equivalent ESWL unit. The patient origin study conducted for Standard 2, an analysis of

patient origin data collected for Standard 3, and the referral data documented for Standard 3 should be used to determine whether such an adverse impact on existing providers is likely to occur.

There are no lithotripsy providers in the three county service area.

5. Adequate Staffing and Services: The applicant should document a plan for recruiting and maintaining a sufficient number of qualified professional and technical staff to provide the ESWL services and must document the following:

a. The existence of an active radiology service and an established referral urological practice;

The applicant complies.

b. The availability within 90 minutes' drive time of acute inpatient services for patients who experience complications; and

The University Of Tennessee Medical Center is 48 minutes away and Oak Ridge Medical Center is 49 minutes away.

c. The fact that all individuals using the equipment meet the training and credentialing requirements of the American College of Surgeons' Advisory Council for Urology.

The applicant complies.

The applicant should also document an ongoing educational plan for all staff included in the ESWL services program.

Dr. Sean DeLair is a Board Certified urologist. Additionally, letters from numerous physicians attached to the application attesting to the need for a local lithotripsy service.

The equipment vendor provides a radiologic technician trained in lithotripsy.

6. ESWL Equipment: Only applications that provide for the provision of ESWL services using equipment that has been approved by the United States Food and Drug Administration for clinical use shall be approvable.

The applicant complies.

7. Quality Control and Monitoring: The applicant should identify and document its intention to participate in a data reporting, quality improvement, outcome monitoring, and peer review system that benchmarks outcomes based on national norms. The system should provide for peer review among professionals practicing in facilities and programs other than the applicant.

The applicant complies.

8. Data Requirements: Applicants should agree to provide the Department of Health and/or the HSDA with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees.

- 9. Transfer and/or Affiliation Agreements:** If an applicant is not a designated Level 1 trauma center, an applicant must document an acceptable plan for the development of transfer and/or affiliation agreements with hospitals in the service area (this criterion does not preclude the development of transfer agreements with facilities outside the applicant's Service Area).

The applicant has a transfer agreement with University of Tennessee Medical Center.

- 10. Access:** In addition to the factors set forth in HSDA Rule 0720-11-.01 (1) (listing the factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant:

a. That is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All three counties in the service area are MUA.

b. That documents that the service area population experiences a prevalence and/or incidence of urinary stones or other clinical conditions applicable to extra-corporeal shock wave lithotripsy services that is substantially higher than the State of Tennessee average; or

The three counties have a higher lithotripsy use rate than the statewide use rate.

c. That is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program.

TH-LMC is not a safety net hospital.